

CA1 HW1180 E53

CA1 HW 1180E53

Canada. DNH. EHD.

80-EHD-53

CANADA-WIDE SURVEY OF NON-IONIZING RADIATION EMITTING
MEDICAL DEVICES. PAR II. ULTRASOUND DEVICES. 1980.

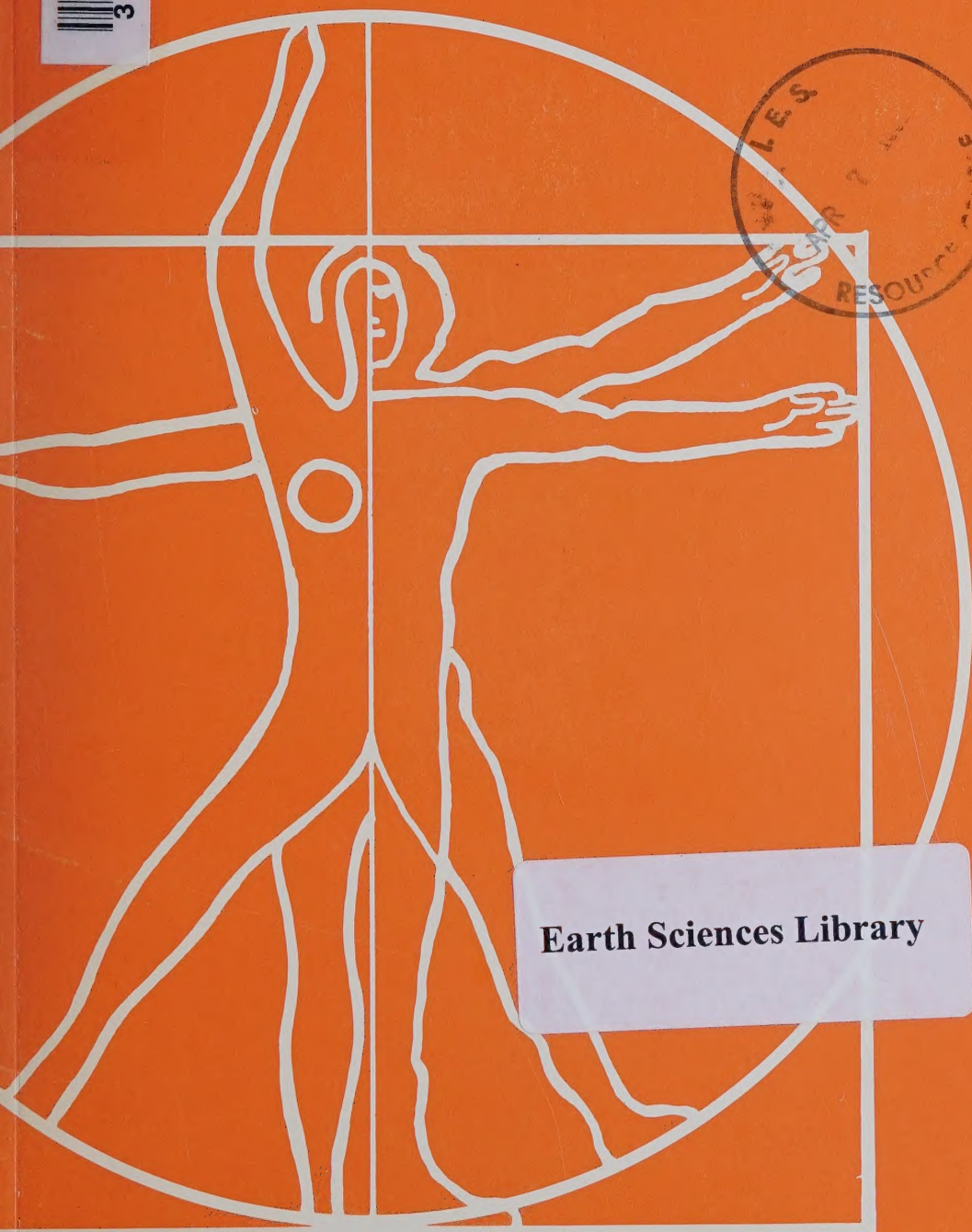
Santé et Bien-être social
Canada

CA1 HW1180 E53

Canada-wide survey of non-ionizing radiation emitting medical devices part II ultrasound devices



3 1761 05688784 7



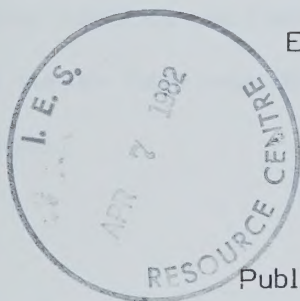
Earth Sciences Library



CANADA-WIDE SURVEY OF NON-IONIZING
RADIATION EMITTING MEDICAL DEVICES

PART II

ULTRASOUND DEVICES



Environmental Health Directorate
Health Protection Branch

Published by Authority of the Minister of
National Health and Welfare

January 1980

COPIES OF THIS REPORT
CAN BE OBTAINED FROM:

Information Directorate,
Department of National Health
and Welfare,
5th Floor,
Brooke Claxton Building,
OTTAWA K1A 0K9

PREFACE

The Radiation Protection Bureau of the Environmental Health Directorate, Health Protection Branch, conducts surveys of devices emitting non-ionizing radiation to investigate potential radiation hazards to personnel and to the general public with the object of developing and recommending safety guidelines and regulations under the Radiation Emitting Devices Act.

This report summarizes the results of the Canada-wide Survey of Ultrasound Medical Devices. The survey was designed and conducted in cooperation with Statistics Canada for the year 1977.

This report was prepared by D.A. Benwell, M.H. Repacholi, W. Curtin and D. Lecuyer of the Radiation Protection Bureau. Computer processing of the survey data was performed by Dr. R.S. McCullough, G.R. Symonds, D. Biggs and D. Hobbs of the Statistics and Data Processing Division, Environmental Health Directorate. The survey form was designed and mailed by the Hospitals Section of Statistics Canada.



Digitized by the Internet Archive
in 2025 with funding from
University of Toronto

<https://archive.org/details/31761056887847>

TABLE OF CONTENTS

	<u>Page</u>
PREFACE	iii
1. INTRODUCTION.....	1
2. DESIGN OF QUESTIONNAIRE	2
3. SURVEY RESULTS	3
THERAPEUTIC ULTRASOUND	3
Number of devices	3
Manufacturers and types of devices.....	3
Treatment	3
Device operators.....	16
Device calibration	16
Adverse effects.....	16
DIAGNOSTIC ULTRASOUND	16
Number of devices	16
Manufacturers and types of devices.....	16
Treatment	26
Device operators.....	26
Device calibration	26
Adverse effects.....	35
OTHER ULTRASOUND DEVICES	35
4. DISCUSSION	36
THERAPEUTIC ULTRASOUND	36
Number of devices	36
Manufacturers and types of devices.....	36
Treatment	38
Device operator and calibration	40
Adverse effects.....	41
DIAGNOSTIC ULTRASOUND	41
Number of devices	41
Manufacturers and types of devices.....	41
Treatment	41
Device operator and calibration	43
Adverse effects.....	43
OTHER ULTRASOUND DEVICES	44

	<u>Page</u>
5. CONCLUSIONS	45
REFERENCES	47
Appendix A - Survey Questionnaire	48
Appendix B - Manufacturers and Distributors of Therapeutic Ultrasound Devices.....	51
Appendix C - Manufacturers and Distributors of Diagnostic Ultrasound Devices.....	52
Appendix D - List of Adverse Effects Reported for Therapeutic Ultrasound Devices.....	53

LIST OF FIGURES

	<u>Page</u>
1. Number and types of facilities reporting use of ultrasound therapy devices	4
2. Geographical distribution of facilities using ultrasound therapy devices	5
3. Percentage of facilities reporting use and upper limit estimated to use therapeutic ultrasound devices	7
4. Parts of body treated by therapeutic ultrasound devices	11
5. Distribution of continuous wave intensity reported for ultrasound therapy devices	14
6. Distribution of continuous wave duration reported for ultrasound therapy devices	15
7. Approximate number of patients/treatments per year with theraptutic ultrasound	17
8. Ultrasound therapy devices; (a) Percentage of calibrated devices; (b) Who Calibrates the devices; (c) Frequency of calibration	20
9. Geographical distribution of facilities (all hospitals) reporting use of ultrasound diagnostic devices	22
10. Percentage of hospitals reporting use and upper limit estimated to use ultrasound devices	24
11. Distribution of continuous wave ultrasound duration reported for ultrasound diagnostic devices	29
12. Distribution of pulsed wave ultrasound duration reported for ultrasound diagnostic devices	30
13. Approximate number of patients/examinations per year with diagnostic ultrasound	31
14. Ultrasound diagnostic devices; (a) Percentage of calibrated devices; (b) Who calibrates the devices; (c) Frequency of calibration	34

LIST OF TABLES

	<u>Page</u>
1. Number of Facilities Using Ultrasound Therapy Devices	6
2. Number of Ultrasound Therapy Devices in Various Provinces	8
3. Number of Ultrasound Therapy Devices in Each Facility Type	8
4. Major Manufacturers and Distributors of Ultrasound Therapy Devices	9
5. Most Commonly Used Ultrasound Therapy Devices by Facility Type	10
6. Parts of the Body Treated by Ultrasound Therapy Devices by Facility Type ...	12
7. Mode and Duration of Treatment of Ultrasound Therapy Devices	13
8. Professions of Operators of Therapeutic Ultrasound Devices	18
9. List of "Other" Categories of Professions Reported Using Ultrasound Therapy Devices.....	18
10. Number of Trained Operators of Ultrasound Therapy Devices	18
11. Ultrasound Therapy Devices Most Commonly Used by Various Professions.....	19
12. Adverse Effects Reported for Therapeutic Ultrasound.....	21
13. Number of Facilities Using Diagnostic Ultrasound Devices	23
14. Number of Diagnostic Ultrasound Devices in Various Provinces	23
15. Number of Diagnostic Ultrasound Devices in Each Facility Type	25
16. Major Manufacturers of Diagnostic Ultrasound Devices.....	25
17. Medical Services in Which Diagnostic Ultrasound Devices Are Used	27
18. Mode and Duration of Examinations Using Diagnostic Ultrasound	28
19. Professions of Operators of Diagnostic Ultrasound Devices	32
20. List of "Other" Categories of Professions Reported Using Diagnostic Ultrasound Devices.....	32
21. Number of Trained Operators of Diagnostic Ultrasound Devices	33
22. Diagnostic Ultrasound Devices Most Commonly Used by Various Professions ..	33
23. Adverse Effects Reported for Diagnostic Ultrasound	35
24. List of "Other" Ultrasound Devices Reported	35
25. Population Distribution by Province in Canada in 1977	37
26. Number of Patients Treated With Therapeutic Ultrasound	39
27. Number of Patients Examined by Diagnostic Ultrasound	44

1. INTRODUCTION

A Canada-wide survey of non-ionizing radiation emitting medical devices was performed from 1977 to 1978. A questionnaire requesting information on medical ultrasound devices was sent out in the fall of 1977, together with a similar questionnaire for short-wave and microwave diathermy devices. The results of the survey will assist in assessing the need, priorities and requirements of regulations limiting non-ionizing radiation from medical devices.

Out of a total of 4254 institutions to which the questionnaire was sent, 2575 (61 percent) returned the completed questionnaire. The following facilities were included in the survey: 1341 hospitals, 1887 chiropractic clinics, 300 physiotherapy clinics and 726 sports medicine clinics. The 111 institutions reporting use of diagnostic ultrasound, all hospitals, were 11 percent of the hospital questionnaires returned. The 972 facilities reporting use of therapeutic ultrasound devices, were 40 percent of the facilities questionnaires returned. No surgical uses of ultrasound were reported.

A total of 8.3 percent of hospitals in Canada reported use of ultrasound diagnostic devices; 22.8 percent of the total facilities in Canada sent forms reported use of therapeutic ultrasound devices.

The questionnaire requested information on the type of equipment used, its maintenance, the number of patients, treatment types, typical exposures, the operator's qualifications and adverse effects. All the returned data referred to the year 1977.

2. DESIGN OF QUESTIONNAIRE

A copy of the questionnaire is enclosed in Appendix A. The questionnaire format was designed by the Hospitals Section of Statistics Canada with the aim of providing as much information as possible on ultrasound medical applications. Whenever possible, questions were answered by checking the appropriate box. However, since there was inadequate information available on manufacturers and model numbers of medical ultrasound devices, this information had to be written on the form by the person completing the questionnaire. The questionnaire was in English on one side and French on the other, and the format selected was much the same as that for microwave and short-wave devices. Three types of ultrasound medical devices were covered by the questionnaire, namely diagnostic, surgical and therapeutic devices.

The questionnaire consists of five basic parts. Part one deals with diagnostic ultrasound devices and requests information on medical services where they are used. Part two deals with therapeutic ultrasound devices and lists parts of the body treated. Part three is the basic one, and in the form of a table provides the following information on diagnostic, therapeutic surgical medical ultrasound devices: device manufacturer, device model, number of patients treated in a period of one year, treatment parameters i.e., operating frequency, exposure intensity and duration, profession and training of the operator, calibration of the equipment and adverse effects (yes or no). Part four elaborates on the operator training, and part five provides details of the adverse effects, if any are reported.

3. SURVEY RESULTS

THERAPEUTIC ULTRASOUND

Number of devices

Replies to the survey on therapeutic applications of ultrasound were received from 972 institutions. Figure 1 shows the number of institutions for each facility type, i.e., hospital, chiropractic clinic, physiotherapy clinic and sports medicine clinic, which use ultrasound therapy devices. The geographical distribution (by province), of facilities using ultrasound therapy devices is shown in Figure 2. Table 1 shows number of facilities in all the provinces using ultrasound therapy devices and is arranged according to facility type. The percentage of facilities reporting use and the upper limit estimated to use ultrasound therapy devices is shown in Figure 3 (100 percent = the total number of each facility sent forms).

A total of 1521 ultrasound therapy devices were reported in use in all the facilities surveyed. Information on the number of devices in various provinces and facility types is summarized in Tables 2 and 3, respectively.

Manufacturers and types of devices

Twenty-five manufacturers of ultrasound therapy devices were reported. Major manufacturers of ultrasound therapy devices are listed in Tables 4 and 5, which also indicate in which facilities various devices were most commonly used in Canada in 1977. It can be seen in Table 4 that two manufacturers constitute 56.6 percent of all ultrasound therapy devices reported in use during the survey.

A complete list of manufacturers reporting ultrasound therapy devices is given in Appendix B.

Treatment

Figure 4 provides information on the parts of the body treated by ultrasound therapy. The numbers indicate treatments reported by all the facilities surveyed. More detailed information on the parts of the body treated is given in Table 6.

The mode (continuous wave or pulsed wave), and duration of treatment are shown in Table 7. The distribution of continuous wave ultrasound intensity and duration reported for ultrasound therapy devices is shown in Figures 5 and 6. These parameters were reported for 87 percent of ultrasound therapy devices.

Information on the frequency of operation of ultrasound therapy devices was given by 41 percent of the respondents, and, of these 51.8 percent reported 0.87 MHz and 31.1 percent reported 1.00 MHz as the operating frequency of ultrasound therapy devices.

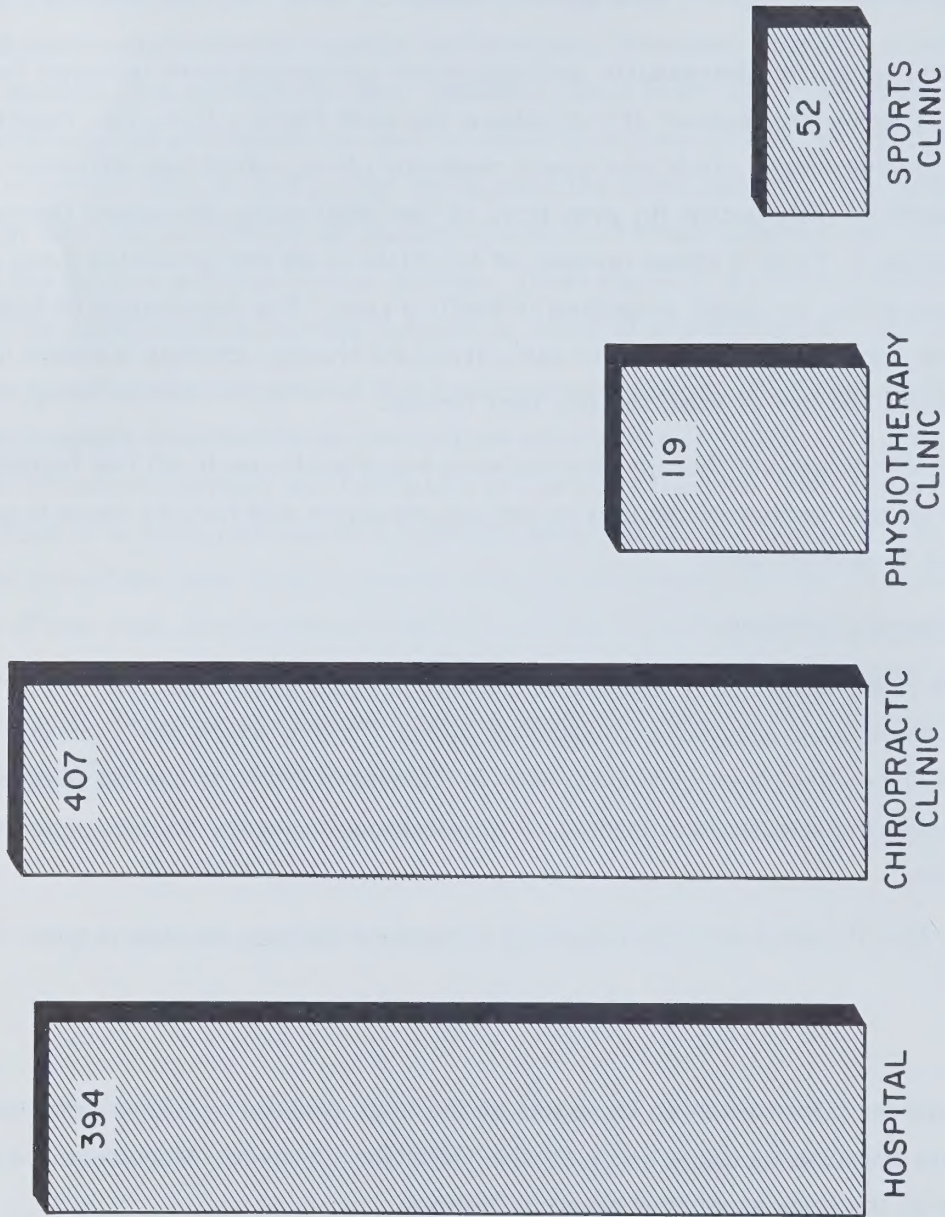


Fig.1 Number and types of facilities reporting use of ultrasound therapy devices.

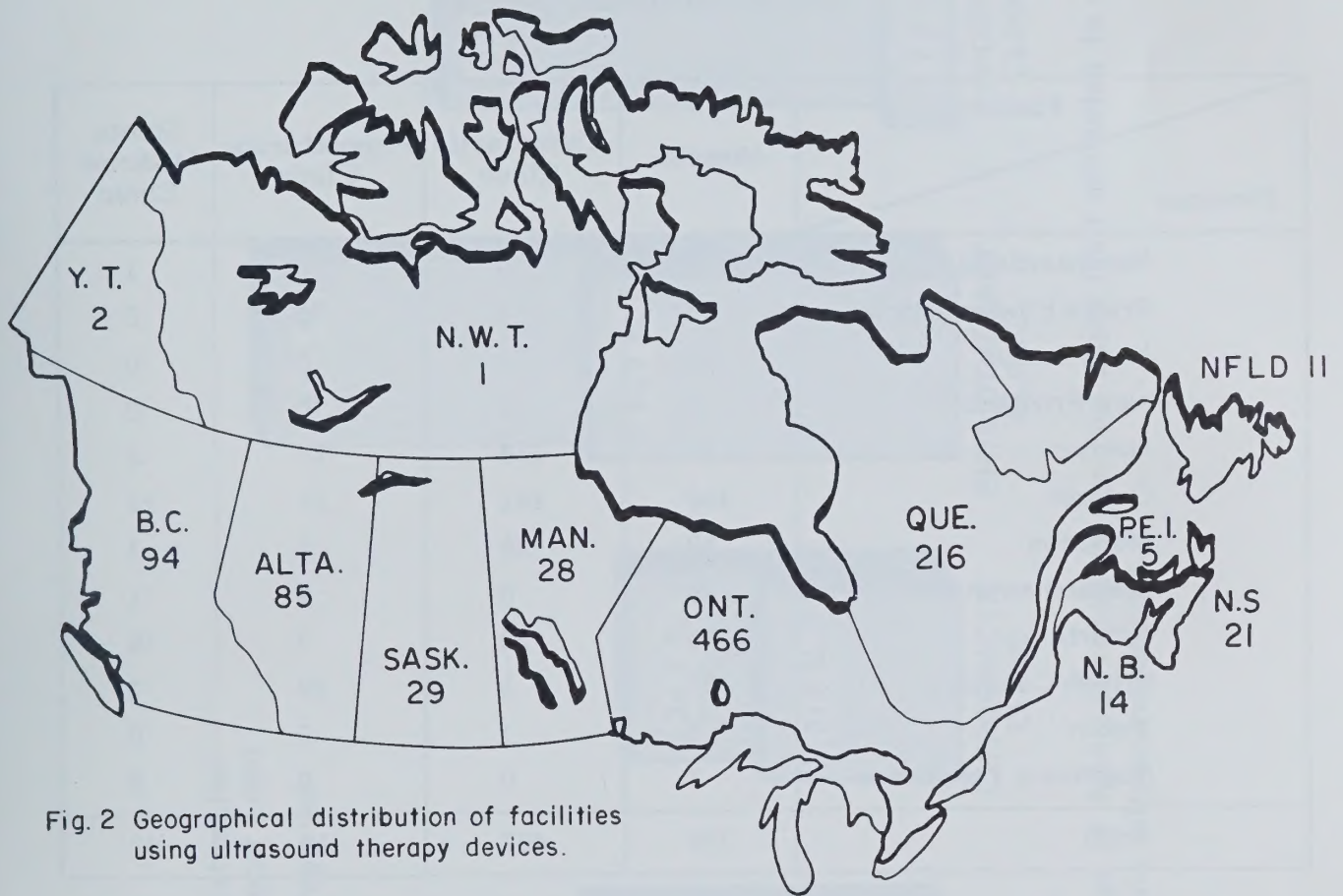


TABLE 1
Number of Facilities Using
Ultrasound Therapy Devices

Province	Facility	Hospital	Chiropractic Clinic	Physiotherapy Clinic	Sports Medicine Clinic
	Newfoundland	10	0	0	1
	Prince Edward Island	3	2	0	0
	Nova Scotia	21	0	0	0
	New Brunswick	12	2	0	0
	Quebec	75	118	17	6
	Ontario	147	241	54	24
	Manitoba	10	14	1	3
	Saskatchewan	19	0	9	1
	Alberta	38	28	9	10
	British Columbia	57	1	29	7
	Yukon	1	1	0	0
	Northwest Territories	1	0	0	0
	Total	394	407	119	52

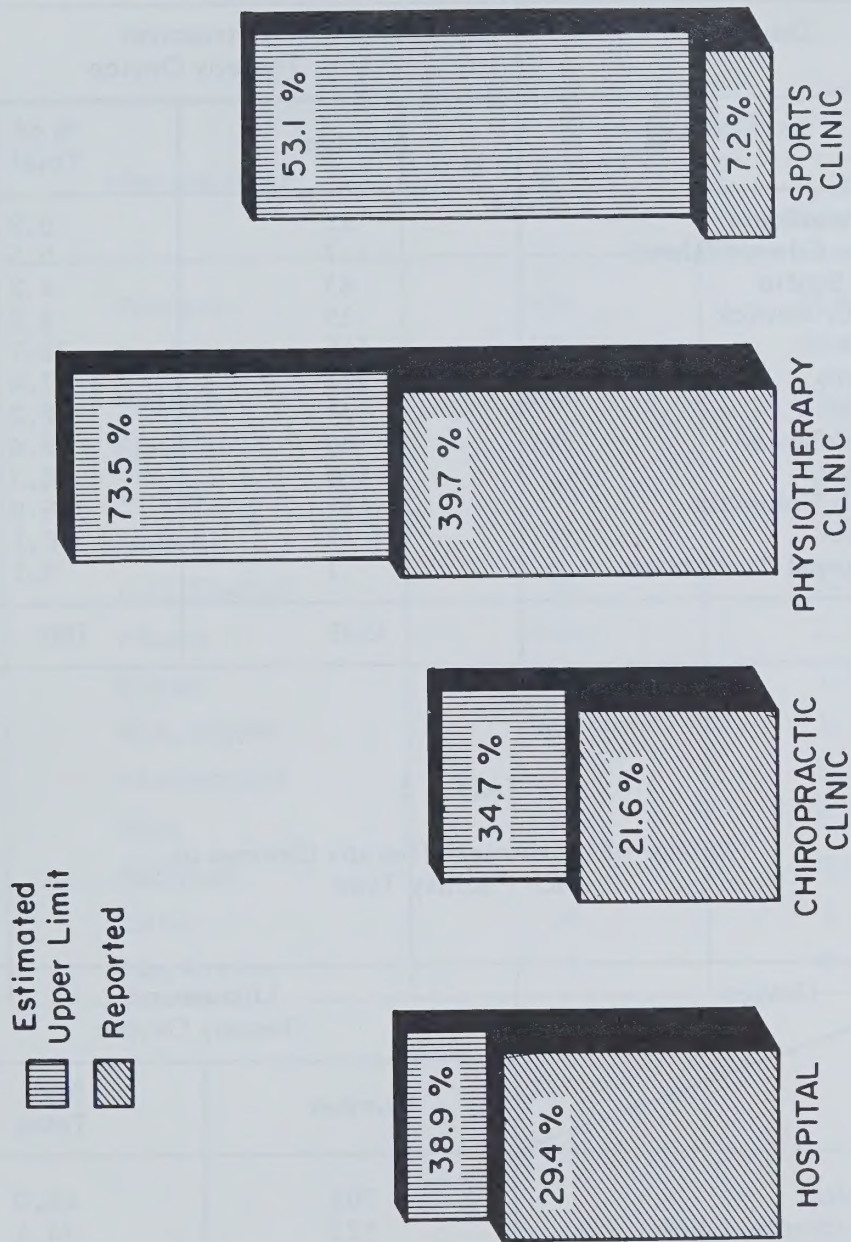


Fig. 3 Percentage of facilities reporting use and upper limit estimated to use therapeutic ultrasound devices.

TABLE 2

Number of Ultrasound Therapy Devices in
Various Provinces

Device Province	Ultrasound Therapy Device	
	Number	% of Total
Newfoundland	12	0.8
Prince Edward Island	7	0.5
Nova Scotia	63	4.2
New Brunswick	19	1.2
Quebec	345	22.7
Ontario	721	47.4
Manitoba	34	2.2
Saskatchewan	40	2.6
Alberta	126	8.3
British Columbia	151	9.9
Yukon	2	0.1
Northwest Territories	1	0.1
Total	1521	100

TABLE 3

Number of Ultrasound Therapy Devices in
Each Facility Type

Device Type of Facility	Ultrasound Therapy Device	
	Number	% of Total
Hospital	701	46.0
Chiropractic Clinic	523	34.4
Physiotherapy Clinic	208	13.7
Sports Clinic	89	5.9
Total	1521	100.0

TABLE 4
Major Manufacturers and Distributors of
Ultrasound Therapy Devices

Manufacturer	Devices Reported	
	Number	% of Total
Siemens	434	28.6
Burdick	426	28.0
Mettler	142	9.3
Birtcher	125	8.2
Amrex	95	6.3
Dallons	87	5.7
H.G. Fischer	59	3.9
Medco	44	2.9
Elmed	28	1.8
R.A. Fisher	16	1.1
Nordelectro	14	0.9
EMS	12	0.8
Richmar	12	0.8
Other	16	1.1
Not Known	9	0.6

TABLE 5
Most Commonly Used Ultrasound Therapy Devices by
Facility Type

Facility Type	Manufacturer	No. of Devices	% of Devices for each Facility Type
Hospital	Siemens	282	40.3
	Burdick	282	40.3
	Birtcher	62	8.9
Chiropractic Clinic	Amrex	89	17.7
	Mettler	85	16.9
	H.G. Fischer	56	11.1
Physiotherapy Clinic	Siemens	80	39.0
	Burdick	58	28.3
	Mettler	27	13.2
Sports Clinic	Burdick	22	42.3
	Siemens	18	34.6
Canadian Athletic Association	Burdick	14	40.0
	Siemens	7	20.0

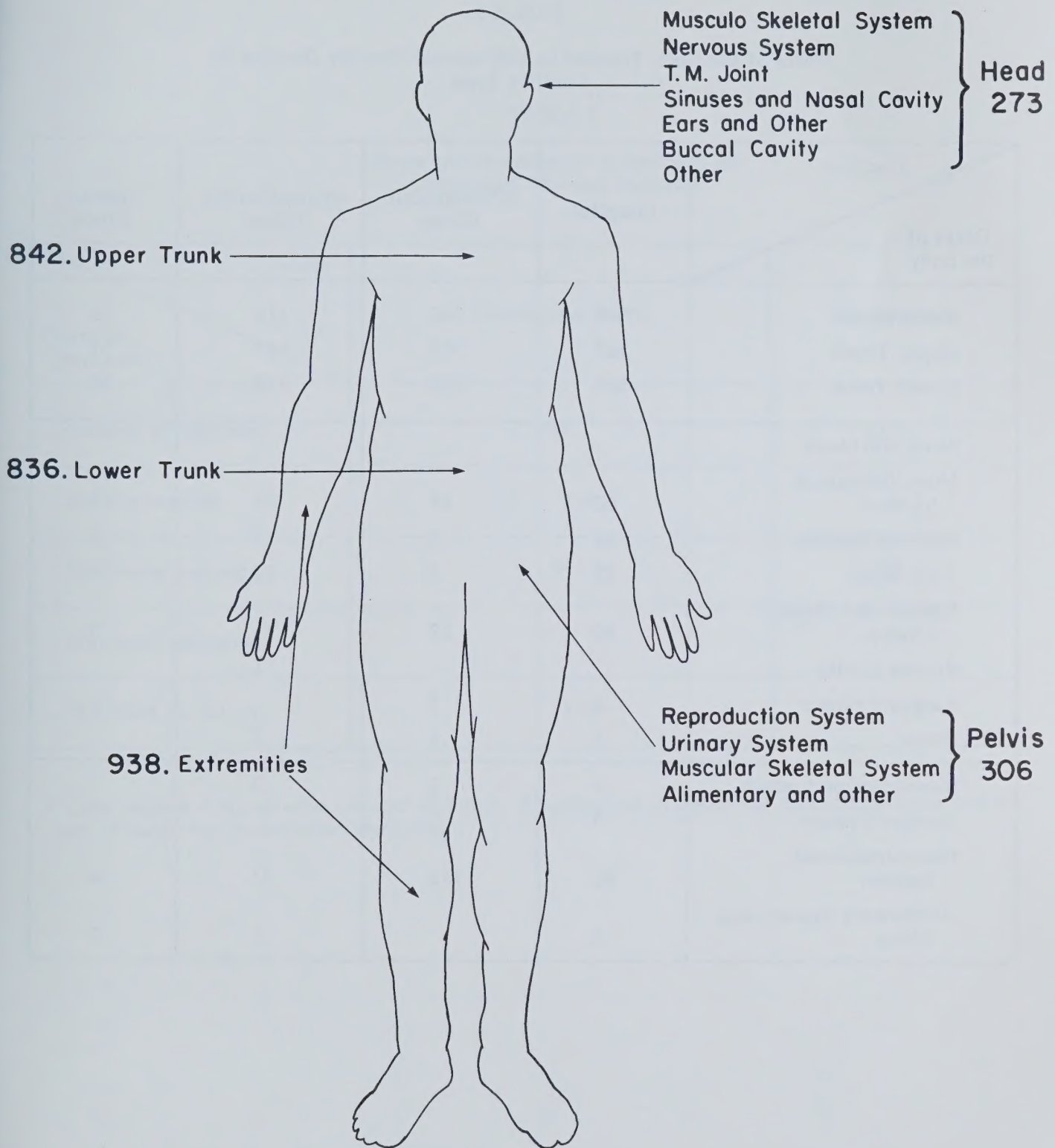


Fig. 4 Parts of body treated by therapeutic ultrasound devices.

TABLE 6

Parts of the Body Treated by Ultrasound Therapy Devices by Facility Type

Facility Parts of the body	Hospital	Chiropractic Clinic	Physiotherapy Clinic	Sports Clinic
Extremities	378	390	118	52
Upper Trunk	367	307	117	51
Lower Trunk	364	304	118	50
Neck and Head				
Musculoskeletal System	60	24	23	7
Nervous System	11	2	3	0
T.M. Joint	32	5	18	6
Sinuses and Nasal Cavity	30	22	14	3
Buccal Cavity			1	
Ears and others	1	1		
Other	6	1	3	
Reproduction System	4	2	3	
Urinary System	3			
Musculoskeletal System	91	142	33	18
Alimentary System and Other	6		1	2

TABLE 7
Mode and Duration of Treatment of
Ultrasound Therapy Devices

Mode Duration (minutes)	Continuous Wave	Pulsed Wave
Number of replies*	1314	618
Mean exposure	7.0	8.3
Maximum exposure	55	30
Minimum exposure	1	2
Standard deviation	3.9	4.6

* Only replies < 60 minutes treated as valid. 9 replies out of range for continuous wave and 6 out of range for pulsed wave duration.

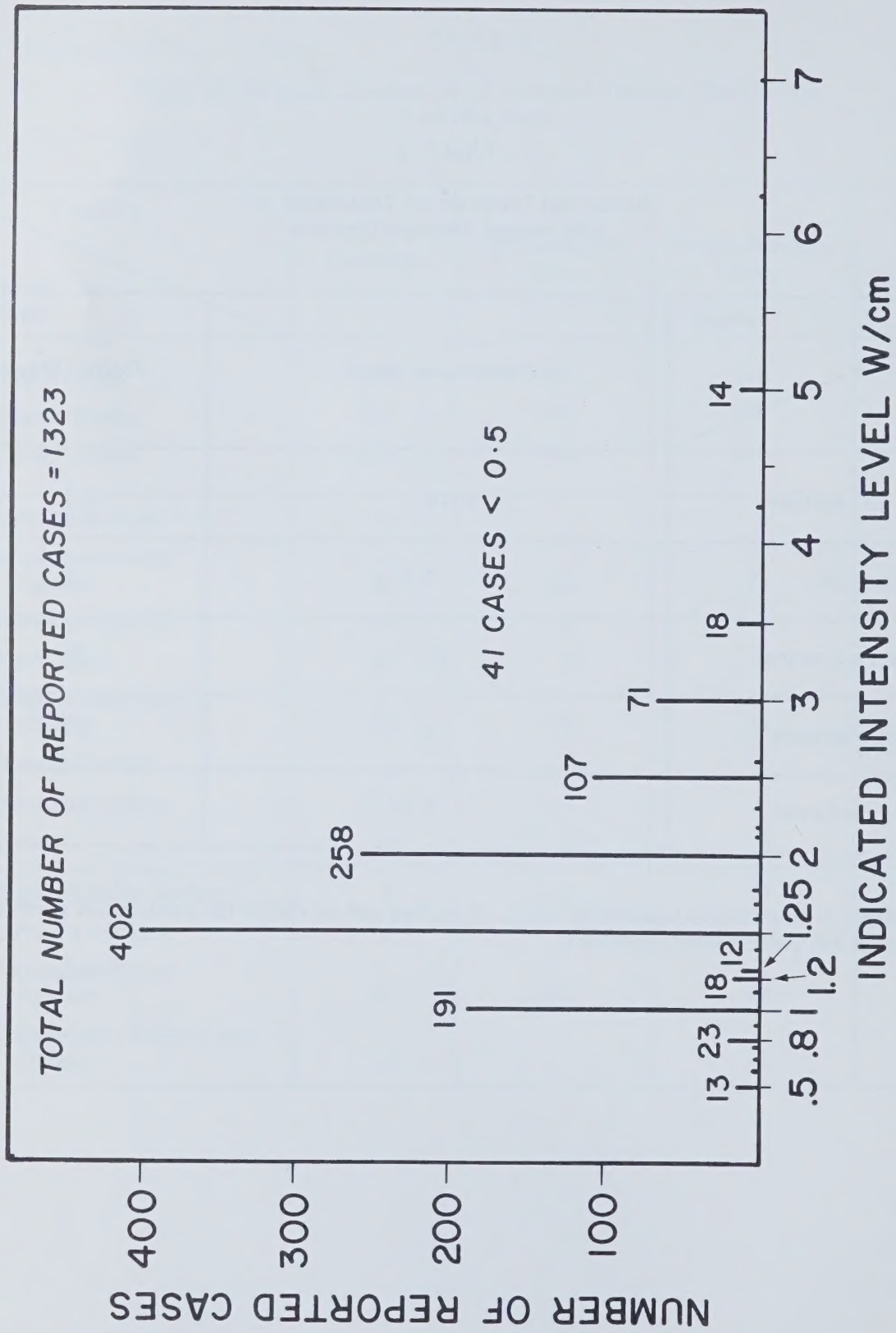


Fig.5 Distribution of continuous wave intensity reported for ultrasound therapy devices.

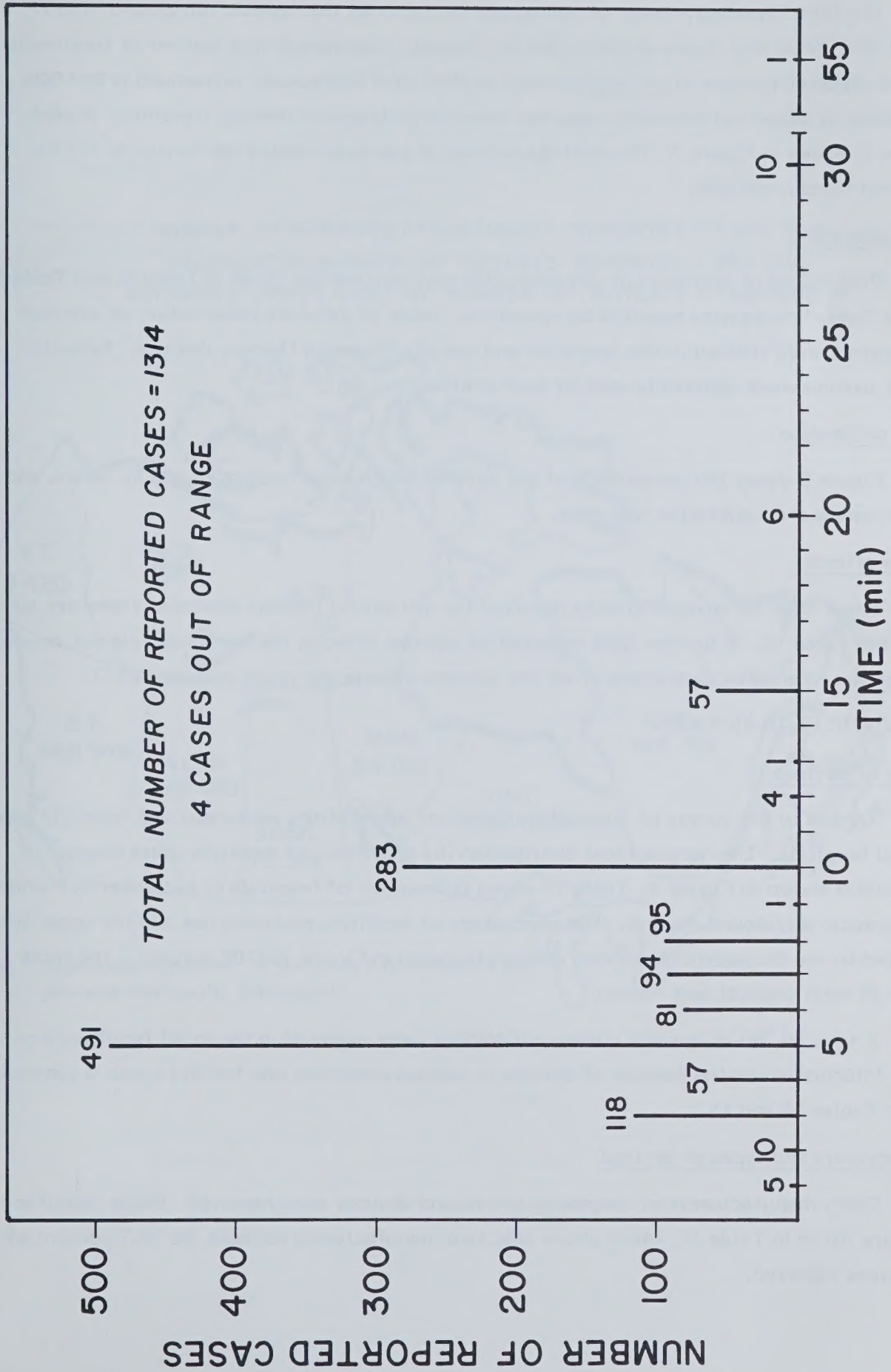


Fig.6 Distribution of continuous wave duration reported for ultrasound therapy devices.

The total reported number of patients/treatments by therapeutic ultrasound in 1977 is 3 920 987. When this figure is corrected to eliminate responses giving number of treatments, the total reported number of patients treated in 1977 with therapeutic ultrasound is 850 000. The number of patients/treatments reported receiving ultrasound therapy treatment in each province is shown in Figure 7. The average number of patients treated per device is 559 for ultrasound therapy devices.

Device operators

Professions of operators of ultrasound therapy devices are given in Table 8, and Table 9 lists the "other" categories reported by operators. Table 10 provides information on whether the operators were trained in the operation and use of ultrasound therapy devices. Table 11 lists the devices most commonly used by each profession.

Device calibration

Figure 8 shows the percentage of the devices which were calibrated and by whom, and how frequently the calibration was done.

Adverse effects

There were 80 adverse effects reported for ultrasound therapy devices. These are summarized in Table 12. A further 1094 reported no adverse effects; the remainder did not answer this question. Verbatim quotations of all the adverse effects are given in Appendix D.

DIAGNOSTIC ULTRASOUND

Number of devices

Replies to the survey of diagnostic ultrasound applications were received from 111 institutions, all hospitals. The geographical distribution (by province), of hospitals using diagnostic ultrasound is shown in Figure 9. Table 13 shows the number of hospitals in each province which use diagnostic ultrasound devices. The percentage of facilities reporting use and the upper limit estimated to use diagnostic ultrasound devices is shown in Figure 10 (100 percent = the total number of each hospital sent forms).

A total of 393 diagnostic ultrasound devices were reported in use in all facilities surveyed. Information on the number of devices in various provinces and facility types is summarized in Tables 14 and 15.

Manufacturers and types of devices

Forty manufacturers of diagnostic ultrasound devices were reported. Major manufacturers are listed in Table 16, which shows that two manufacturers account for 28.7 percent of the devices reported.

TABLE II

Profession of Operator of
Therapeutic Ultrasound Devices

Operator's Profession	Number of devices used by each professional category	Percent
Medical Physiotherapist	10.9	0.9
Physiotherapist	22.7	2.7
Chiropractor	24.3	2.3
Ultrasound technician	7.3	0.7
Other	3.4	0.3

NUMBER OF PATIENTS/TREATMENTS REPORTED = 3 920 987

CALCULATED NUMBER OF PATIENTS REPORTED = 850 000

ESTIMATED UPPER LIMIT OF NUMBER OF PATIENTS = 1 500 000

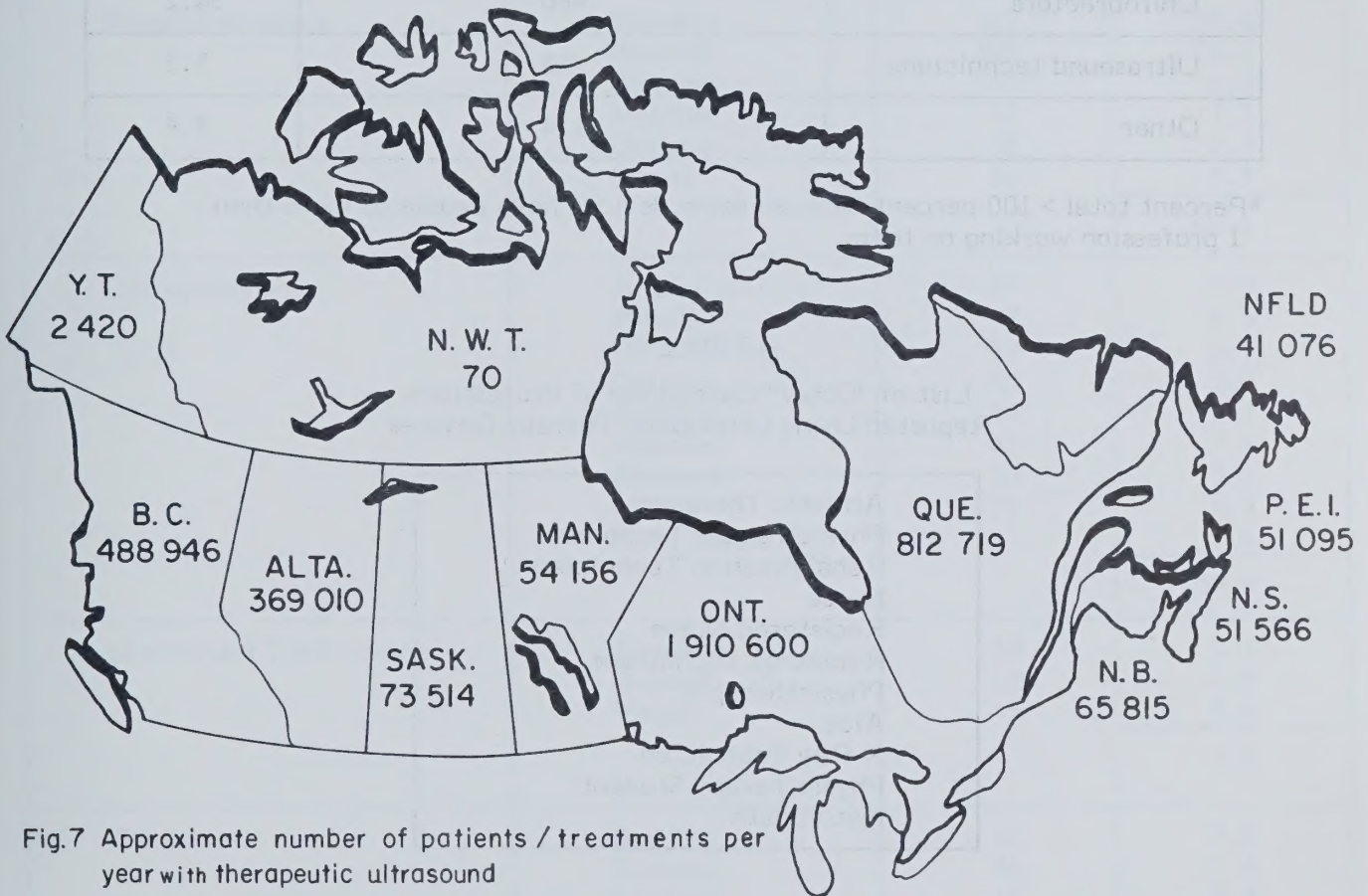


Fig.7 Approximate number of patients / treatments per year with therapeutic ultrasound

TABLE III

Number of Trained Operators of Ultrasound
Therapy Devices

Operator Trained	Operator Untrained	No reply
Number	Number	Number
1103	98	320
72.5	6.4	21.1

TABLE 8

Professions of Operators of
Therapeutic Ultrasound Devices

Operator's Profession	Number of devices used by each professional category	Percent*
Medical doctors	13	0.9
Physiotherapists	879	62.7
Chiropractors	480	34.2
Ultrasound technicians	45	3.2
Other	134	9.6

*Percent total > 100 percent because some devices have people of more than 1 profession working on them.

TABLE 9

List of "Other" Categories of Professions
Reported Using Ultrasound Therapy Devices

Athletic Therapist Physiotherapy Technician Rehabilitation Technician Nurse Registered Nurse Radiology Technician Physiotherapist Aide X-Ray Technician Physiotherapy Student Naturopath
--

TABLE 10

Number of Trained Operators of Ultrasound
Therapy Devices

Operator Trained		Operator Untrained		No reply	
Number	%	Number	%	Number	%
1103	72.5	98	6.4	320	21.1

TABLE 11

Ultrasound Therapy Devices Most Commonly Used By
Various Professions

Profession	Ultrasound Therapy Device	Number	Percent
Medical Doctors	Burdick Birtcher	5	0.4
		4	0.3
			0.7
Physiotherapists	Siemens	362	25.8
	Burdick	320	22.8
	Birtcher	62	4.4
	Mettler	47	3.3
	Dallons	38	2.7
	Elmed	16	1.1
			60.1
Chiropractors	Amrex	83	5.9
	Mettler	77	5.5
	H.G. Fischer	52	3.7
	Dallons	45	3.2
	Burdick	44	3.1
	Birtcher	43	3.1
	Siemens	43	3.1
	Medco	32	2.2
	R.A. Fisher	15	1.1
			30.9
Ultrasound Technicians	Siemens	16	1.1
	Burdick	12	0.9
	Medco	5	0.4
			2.4
Other	Burdick	40	2.9
	Siemens	34	2.4
	Mettler	12	0.9
	Birtcher	12	0.9
	Medco	8	0.6
			7.7

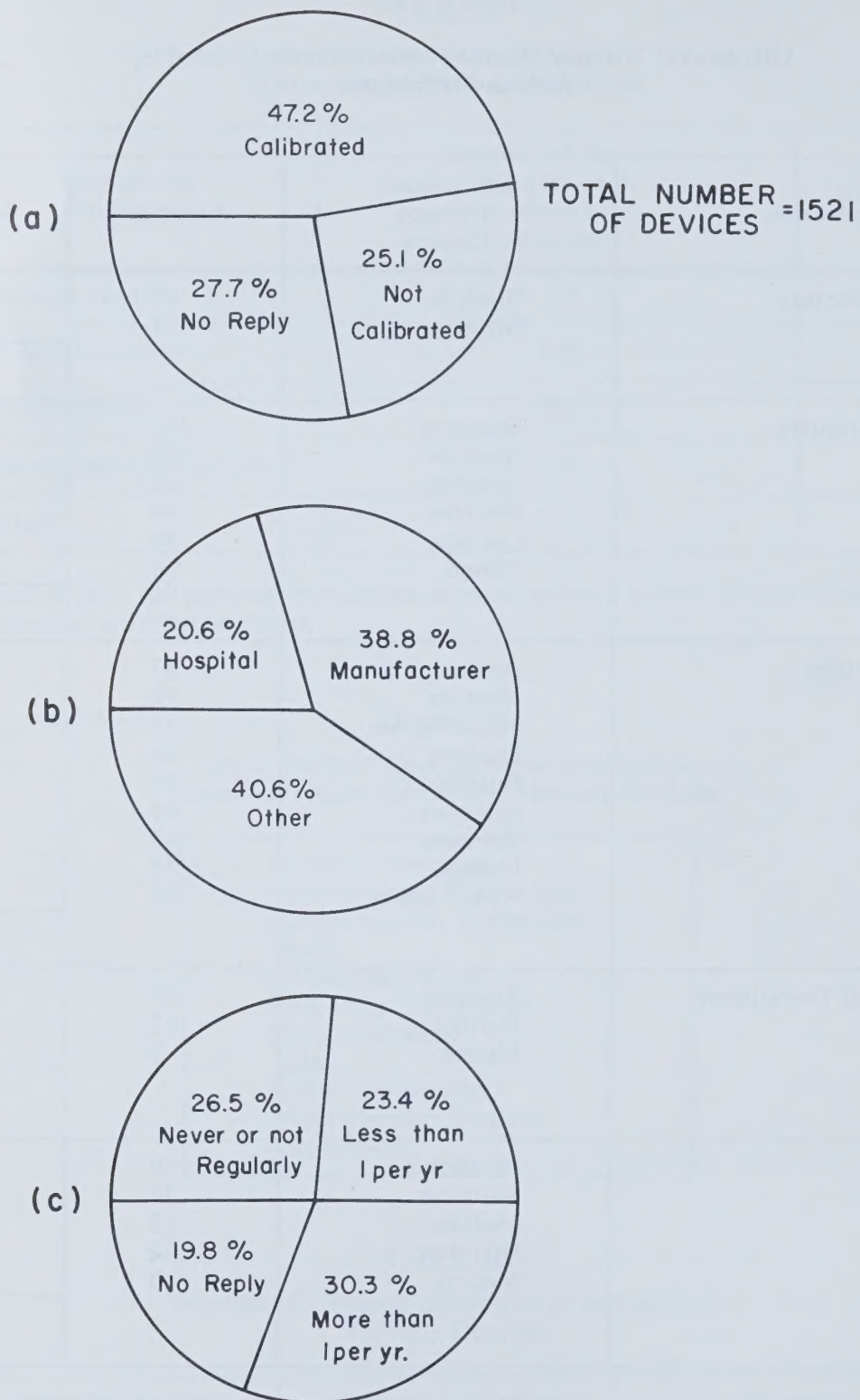


Fig. 8 Ultrasound Therapy Devices
(a) Percentage of calibrated devices (b) Who calibrates the devices (c) Frequency of calibration

TABLE 12

Adverse Effects Reported For
Therapeutic Ultrasound

Adverse Effects	Facility				Total
	Hospital	Chiropractic Clinic	Physiotherapy Clinic	Sports Clinic	
Pain/discomfort	22	7	16	2	47
Epidermal Irritation*	3	5	2		10
Burns/Heat	3	2			5
Dizziness/ Nausea/ Fatigue	5	1	1		7
Patient/ operator anxiety	1	1			2
Ear damage to operator**	1				1
Usual Contraindications	1				1
Not stated	1	3	3		7
Total	37	19	22	2	80

* Usually due to coupling agent used.

** Not verified in contact with hospital.

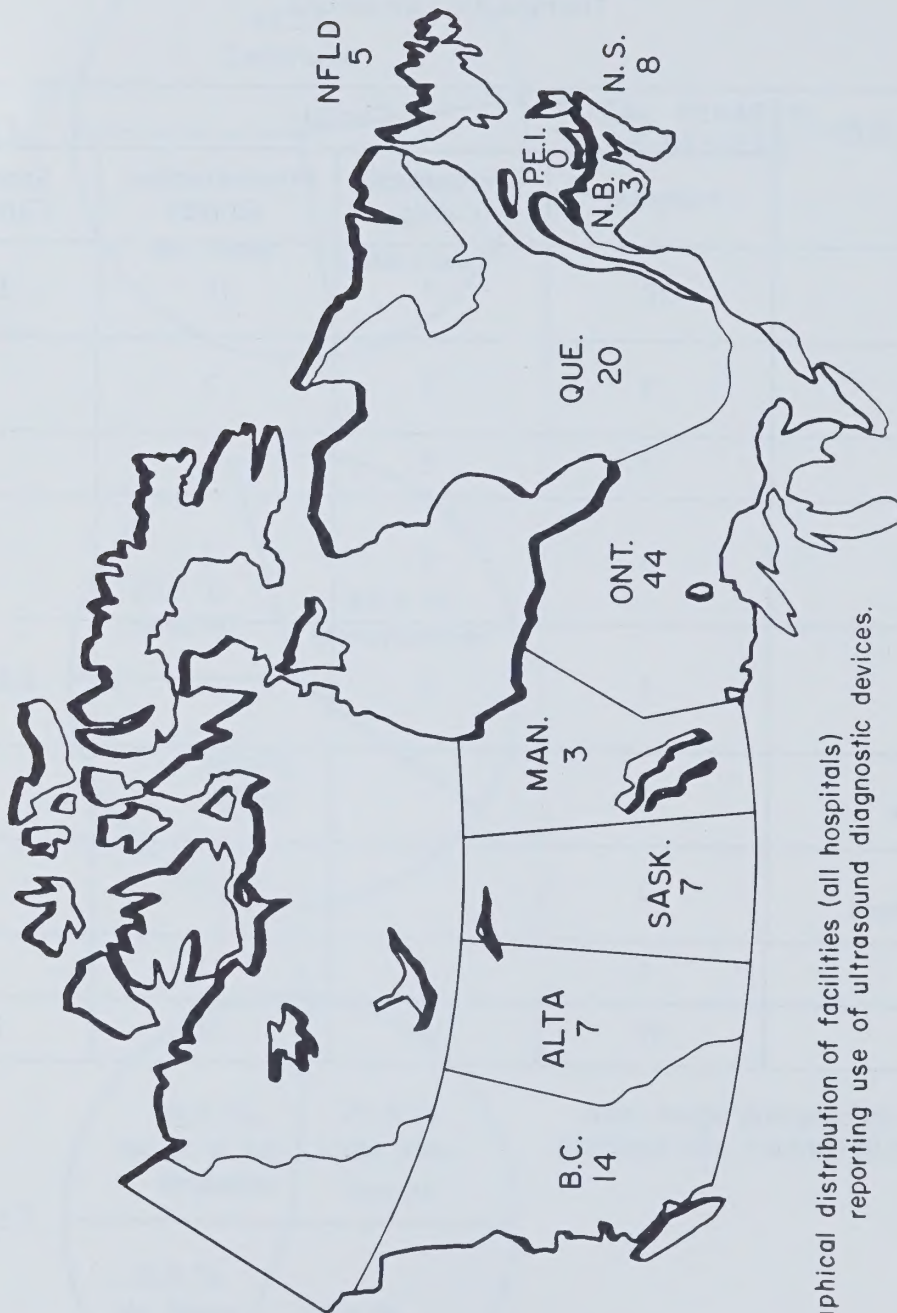


Fig. 9 Geographical distribution of facilities (all hospitals) reporting use of ultrasound diagnostic devices.

TABLE 13
Number of Facilities Using
Diagnostic Ultrasound Devices

Province	Facility	Hospital
	Newfoundland	5
	Nova Scotia	8
	New Brunswick	3
	Quebec	20
	Ontario	44
	Manitoba	3
	Saskatchewan	7
	Alberta	7
	British Columbia	14
	Total	111

TABLE 14
Number of Diagnostic Ultrasound Devices in
Various Provinces

Province	Ultrasound Diagnostic Device	
	Number	% of Total
Newfoundland	8	2.0
Nova Scotia	23	5.9
New Brunswick	10	2.6
Quebec	77	19.6
Ontario	191	48.6
Manitoba	9	2.3
Saskatchewan	8	2.0
Alberta	15	3.8
British Columbia	52	13.2
Total	393	100.0

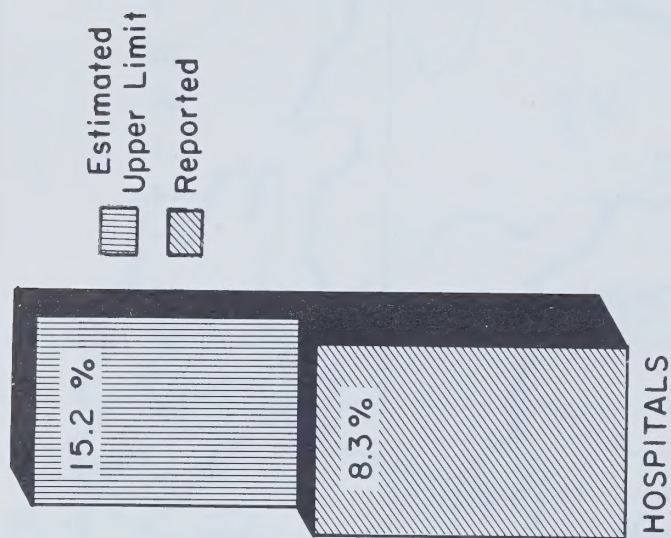


Fig. 10 Percentage of hospitals reporting use and upper limit estimated to use diagnostic ultrasound devices.

TABLE 15

Number of Diagnostic Ultrasound Devices
in Each Facility Type

Device Facility	Ultrasound Diagnostic Devices	
	Number	% of Total
Hospital	393	100 %

TABLE 16

Major Manufacturers of
Diagnostic Ultrasound Devices

Manufacturer	Devices Reported	
	Number	% of Total
Picker	65	16.5
Parks	48	12.2
S.K.I.	35	8.9
Unirad	27	6.9
Hewlett Packard	27	6.9
ADR	23	5.9
Hoffman Laroche	23	5.9
Sonicaid	23	5.9
Corometrics	20	5.1
Medsonics	13	3.3
Hoffrel	10	2.5
Highstoy	9	2.3
Searle	6	1.5
Kontron	6	1.5
Remainder	58	14.7

A complete list of manufacturers reported for diagnostic ultrasound devices is given in Appendix C.

Treatment

Table 17 provides information on the medical services in which diagnostic ultrasound devices are used. The numbers indicate examinations reported by all the facilities surveyed.

The mode (continuous wave or pulsed wave) and duration of treatment are shown in Table 18. These parameters were reported for 25 percent of diagnostic ultrasound devices. Figures 11 and 12 show the distribution of continuous and pulsed wave ultrasound duration reported. Only 4 percent of respondents gave meaningful information on the duty cycle of pulsed wave ultrasound.

There were 73 percent of the respondents who gave information on the frequency of operation of diagnostic ultrasound devices. Of these 22.9 percent reported 2.25 MHz, 12.3 percent reported 2.00 MHz, and 12.3 percent reported 3.5 MHz as the operating frequency.

The total reported number of patients/examinations in 1977 by diagnostic ultrasound is 1 216 700. When this figure is corrected to eliminate responses giving the number of examinations, the total reported number of patients examined in 1977 by diagnostic ultrasound is 340 000. The number of patients/examinations reported for diagnostic ultrasound in each province is shown in Figure 13. The average number of patients examined per device is 865 for diagnostic ultrasound devices.

Device operators

Professions of operators of diagnostic ultrasound devices are given in Table 19, while Table 20 lists the other professions reported by operators. Table 21 provides information on whether the operators were trained in the use of diagnostic ultrasound devices. Table 22 lists the diagnostic ultrasound devices most commonly used by various professions.

Device calibration

Figure 14 shows the percentage of the devices which were calibrated and by whom, and how frequently the calibration was done.

TABLE 17
Medical Services in Which Diagnostic
Ultrasound Devices Are Used

Cardiology and Cardiovascular Surgery	336
Obstetrics	301
Radiology	272
Neurology	210
General Surgery	153
Urology	124
Ophthalmology	49
Emergency	89
Pediatrics	21
Research	5
Fractures	5
General Abdominal Scan	3
Internal Medicine	2

TABLE 18
Mode and Duration of Examinations Using
Diagnostic Ultrasound

Mode Duration (minutes)	Continuous Wave	Pulsed
Number of replies*	98	101
Mean Exposure	12.13	20.6
Maximum Exposure	60	60
Minimum Exposure	1	2
Standard Deviation	13.9	18.0

*Only replies < 60 minutes treated as valid.

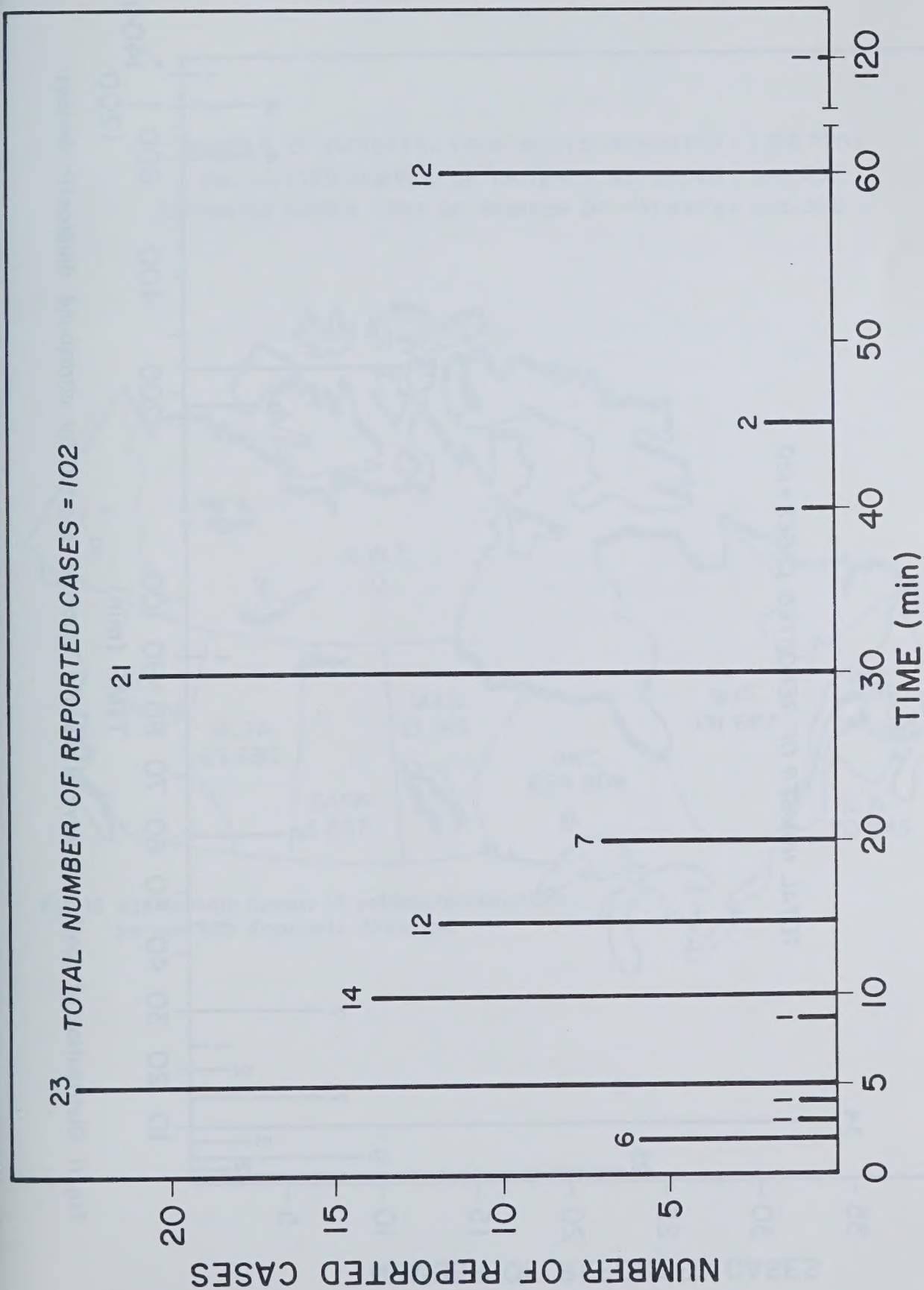


Fig 12. Distribution of pulsed wave ultrasound duration reported for ultrasound diagnostic devices

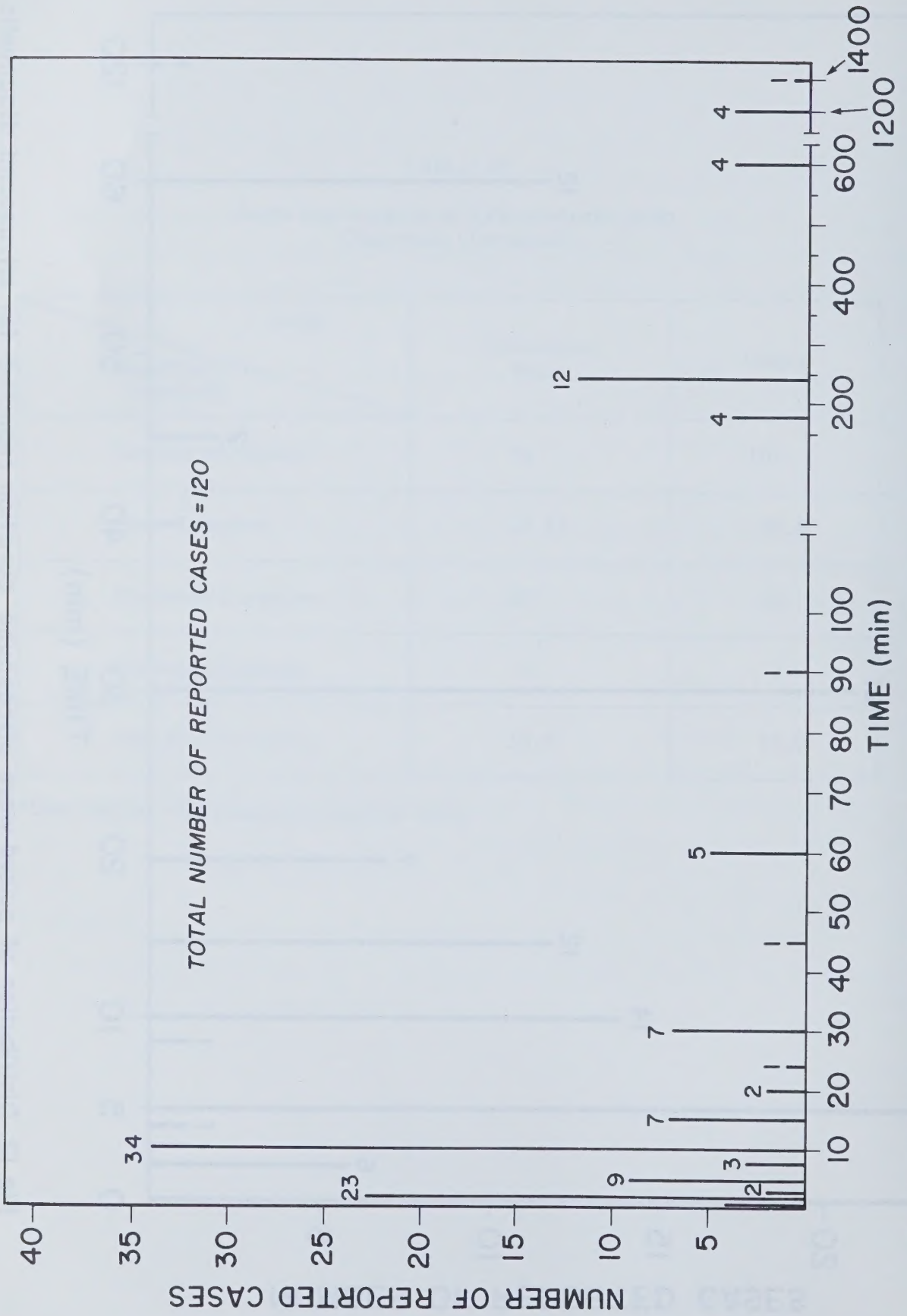


Fig. 11 Distribution of continuous wave ultrasound duration reported for ultrasound diagnostic devices.

NUMBER OF PATIENTS / TREATMENTS REPORTED = 1 216 770
CALCULATED NUMBER OF PATIENTS REPORTED = 340 000
ESTIMATED UPPER LIMIT OF NUMBER OF PATIENTS = 620 000

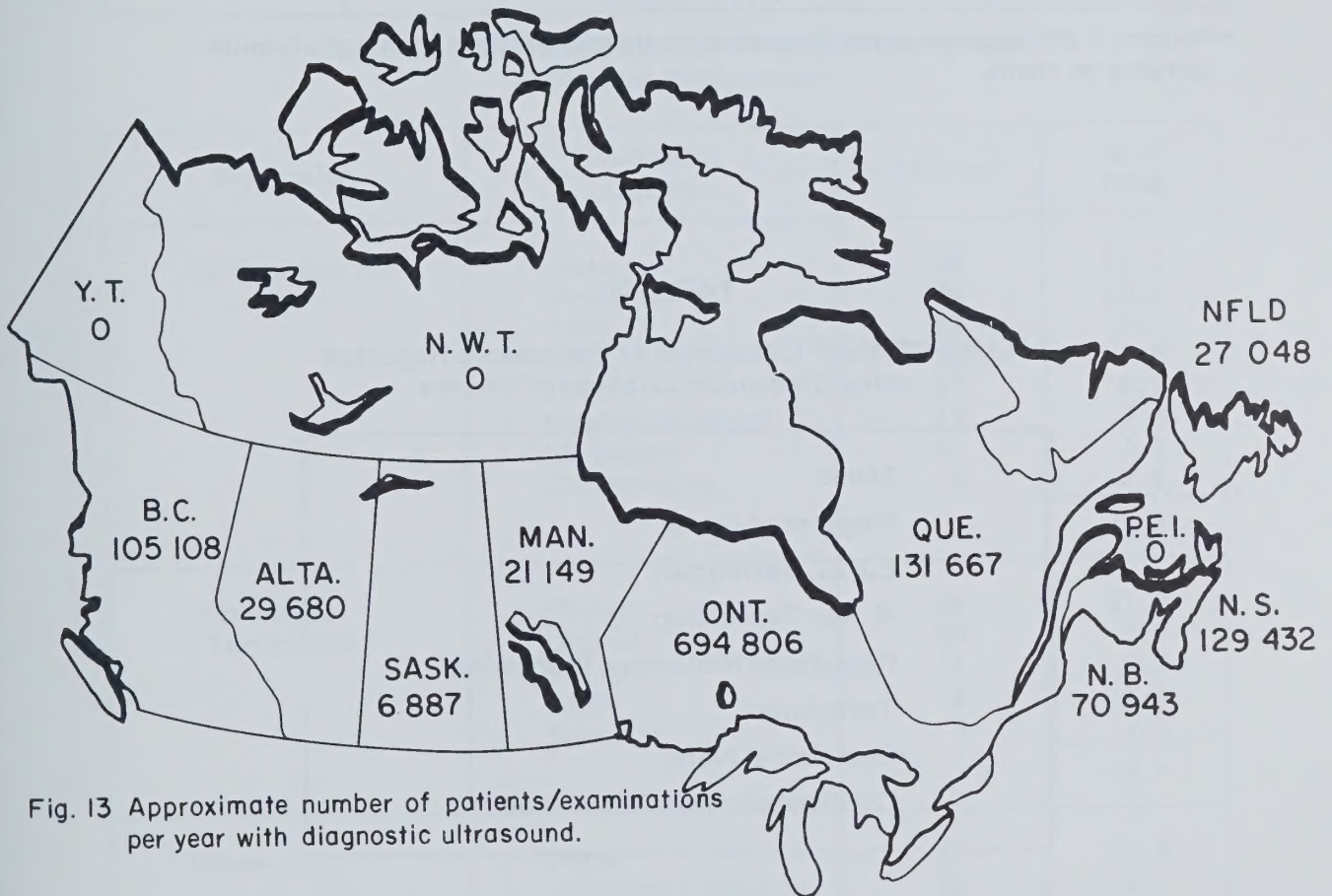


Fig. 13 Approximate number of patients/examinations per year with diagnostic ultrasound.

TABLE 19

Professions of Operators of
Diagnostic Ultrasound Devices

Operator's Profession	Number of Devices Used by Each Professional Category	Percent*
Medical Doctors	225	62.2
Ultrasound Technicians	107	31.0
Other	193	55.9

*Percent > 100 because some devices have people of more than 1 profession working on them.

TABLE 20

List of "Other" Categories of Professions Reported
Using Diagnostic Ultrasound Devices

Nurse
Registered Nurse
E.E.G. Technician
X-Ray Technician
Registered Radiology Technician
Technician
Obstetrical Nurse
Cardiorespiratory Technician

TABLE 21
Number of Trained Operators of
Diagnostic Ultrasound Devices

Operator Trained		Operator Untrained		No Reply	
Number	%	Number	%	Number	%
174	44.3	135	34.4	84	21.4

TABLE 22
Diagnostic Ultrasound Devices Most Commonly Used
by Various Professions*

Profession	Diagnostic Device	Number	% of Total
Medical Doctor	Parks	38	11.0
	Picker	36	10.4
	ADR	21	6.1
	S.K.I.	20	5.8
	Unirad	17	4.9
	Hewlett Packard	13	3.8
	Medsonics	11	3.2
	Corometrics	9	2.6
			47.8
Ultrasound Technician	Picker	38	11.0
	Unirad	20	5.8
	S.K.I.	11	3.2
	ADR	8	2.3
	Searle	5	1.4
			23.7
Other	Parks	41	11.9
	Hoffman-Laroche	21	6.1
	S.K.I.	17	4.9
	Corometrics	17	4.9
	Picker	16	4.6
	Hewlett Packard	16	4.6
	Sonicaid	12	3.5
	Medsonics	7	2.0
			42.5

*345 devices reported

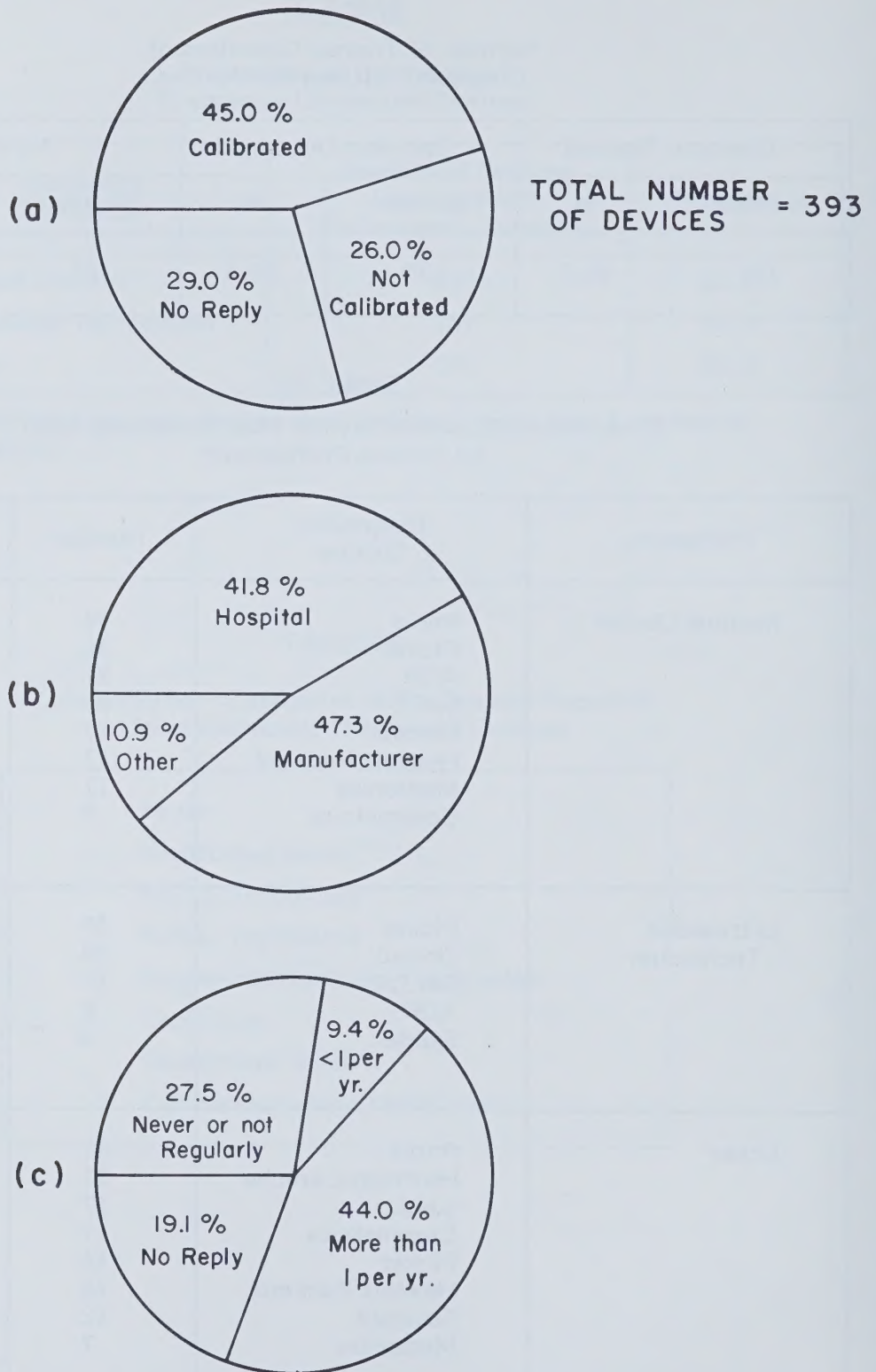


Fig. 14. Ultrasound Diagnostic Devices

(a) Percentage of calibrated devices (b) Who calibrates the devices (c) Frequency of calibration

Adverse effects

Adverse effects reported for diagnostic ultrasound are shown in Table 23. Only two were reported; one did not state what the adverse effect was and the other stated a false diagnosis, although this is not generally counted as an adverse effect. A further 328 reported no adverse effects, and 63 did not answer this question.

OTHE ULTRASOUND DEVICES

There were 67 other ultrasound devices reported and these are shown in Table 24. They consist of mainly nebulizers, alarm systems and cleaners. No further use was made of this information.

TABLE 23

Adverse Effects Reported for
Diagnostic Ultrasound

Adverse Effect	Number
False diagnosis	1
Not stated	1

TABLE 24

List of "Other" Ultrasound Devices Reported

Make	Type of Device	Number Reported
Sonalarm	Alarm	35
Mistogen	Nebulizer	14
Devilbiss 65	Nebulizer	7
Devilbiss 35	Nebulizer	5
Bendix	Cleaner/Nebulizer	2
Ritter	Thermograph	2
IVAC	Thermograph	1
Telecust	Not Known	1
Total		67

4. DISCUSSION

THERAPEUTIC ULTRASOUND

Number of devices

There were 22.8 percent of the facilities sent questionnaires that reported use of therapeutic ultrasound. An estimate of the number of facilities using therapeutic ultrasound was made, based on the ratio of completed filled returns to blank signed returns for each facility. This gave a total estimate of 39.7 percent of facilities using therapeutic ultrasound. However, this will most likely overestimate the number of facilities and is, therefore, used as an upper bound. Thus, there were between 23 percent and 40 percent of facilities using therapeutic ultrasound in Canada in 1977. The wide difference between the upper and lower estimated number of facilities is due to the large number of forms not returned from some facilities.

Therapeutic ultrasound is used more in hospitals and chiropractic clinics than in physiotherapy and sports clinics (Figure 1, Tables 1 and 3). However, Figure 3 shows that therapeutic ultrasound devices are used by a greater percentage of physiotherapy clinics (39.7 percent), than by hospitals (29.4 percent), or chiropractic clinics (21.6 percent). The estimated upper limit for physiotherapy clinics is 73.5 percent, indicating that between 40 percent and 74 percent of physiotherapy clinics used therapeutic ultrasound in 1977.

The regional distribution of facilities using ultrasound therapy devices (Figure 2, Table 1), is roughly proportional to the population of each province, with the exception of Ontario (Table 25). Slightly under half of the facilities using therapeutic ultrasound are located in Ontario, which also accounts for 47 percent of the devices used. Ontario and Quebec, together account for 70 percent of the devices used (Table 2). British Columbia and Alberta have the next highest use of devices, with 10 percent and 8.3 percent respectively of the total number of devices.

The average number of devices per facility reporting use of therapeutic ultrasound is 1.6. Apart from Nova Scotia, where there are an average of 3 devices per facility, the remaining provinces do not vary significantly, having between 1.0 and 1.6 devices per facility (Table 2, Figure 2). There are 46 percent of ultrasound therapy devices located in hospitals.

Manufacturers and types of devices

In Appendix B 25 manufacturers and distributors of therapeutic ultrasound devices are listed. Not all of these have been identified or located. However, those unidentified account for only 0.6 percent of the total number of therapy devices (Table 4). The list itself is condensed from the original returns, with corrections made for spelling errors and confusion between the manufacturer and device model names. The two main devices used, Siemens and Burdick, accounted for 56.6 percent of the total devices reported. The ten most commonly used devices accounted for 95.8 percent of the total devices reported (Table 4).

TABLE 25

Population Distribution by
Province in Canada in 1977

Province	Population in 1977	
	Number - 1000	%
Newfoundland	564	2.4
P.E.I.	120	0.5
Nova Scotia	835	3.6
New Brunswick	686	2.9
Quebec	6 283	27.0
Ontario	8 374	36.0
Manitoba	1 031	4.4
Saskatchewan	936	4.0
Alberta	1 900	8.2
B.C.	2 498	10.7
Yukon	21	0.1
Northwest Territories	43	0.2
Canada	23 291	100 %

No attempt was made to list the device model numbers since a great many of these were erroneously reported.

Treatment

Those facilities reporting treatment indicated extremities, upper trunk and lower trunk as the most frequently treated parts of the body. Approximately 950 facilities replied (Figure 4, Table 6). Each facility type reported the same major parts of the body treated (Table 6). Approximately 270 facilities reported treatment of the neck and head, and just over 300 facilities reported treatment for the pelvic area (Figure 4).

The continuous wave mode was used more than twice as often as pulsed wave mode of ultrasound. The mean exposure time for continuous wave mode was 7 minutes, and more than 8 minutes for pulsed wave mode (Table 7). Exposure times greater than or equal to 60 minutes occurred 15 times in more than 1900 replies (less than 0.8 percent), and were neglected as being erroneously reported. The distribution of continuous wave mode duration times reported is shown in Figure 6, most replies being between 3 and 10 minutes, with 5 minutes the most commonly reported.

Whilst pulsed wave mode was reported by 40.6 percent of the respondents, only 11 percent reported a meaningful duty cycle (between 0 and 100 percent), preventing an exposure calculation from being made.

Of the respondents 86 percent gave information on continuous wave mode intensity levels. Figure 5 shows the distribution of indicated intensity levels in watts per square centimetre (W/cm^2) for all but 86 replies, which were out of the range plotted. All known ultrasound therapy devices operate at less than or equal to $4 \text{ W}/\text{cm}^2$, indicating a considerable number of erroneous replies. The most commonly reported intensity level used was $1.5 \text{ W}/\text{cm}^2$ (30.6 percent of the respondents gave this value), 19.6 percent at $2 \text{ W}/\text{cm}^2$, 14.4 percent at $1 \text{ W}/\text{cm}^2$, 8.1 percent at $2.5 \text{ W}/\text{cm}^2$, 5.4 percent at $3 \text{ W}/\text{cm}^2$. These account for 80 percent of the total replies.

A total of 41 percent of the respondents indicated the ultrasound frequency of operation. Of the ultrasound devices for which frequency was identified, 51.8 percent operated at 0.87 MHz, and 31.1 percent at 1.00 MHz.

More than 3.9 million patients/treatments were reported for therapeutic ultrasound in 1977. A detailed look at the completed returns shows that the actual number of reported patients is approximately 850 000 (Figure 7, Table 26). The reason for this is that the question had asked for the number of patients treated per device in 1977, but in the reported returns there was some confusion between the number of patients treated, the number of patients treated

TABLE 26
Number of Patients Treated With
Therapeutic Ultrasound

No. Facility	No. of forms sent out	No. of com- pleted forms returned	No. of blank signed forms returned	No. of patients/ treat- ments reported	No. of patients reported	Estimated upper limit of number of patients treated
Hospitals	1 341	394	619	1 763 421		
Chiropractic Clinics	1 887	407	767	1 096 812		
Physio- therapy Clinics	300	119	43	794 660		
Sports Clinics	726	52	46	226 094		
Total	4 254	972	1 475	3 920 987	850 000	1 500 000

per device, and the number of treatments. Detailed analysis of the replies showed that 80 percent reported 5000 or less patients treated per year per device, 2 percent reported 5000 - 9000 patients treated per year per device, and 18 percent reported 10 000 patients treated per year per device. In addition, the number of replies decreased steadily for an increasing number of patients, except for the large number reporting 10 000 patients. A check with several facilities confirmed that 5000 patients per year per device was a reasonable maximum limit. A recalculation on this basis gives 850 000 patients treated by therapeutic ultrasound in 1977.

In addition, an estimate of the total number of patients treated using therapeutic ultrasound was based on the ratio of completed filled returns to blank signed returns for each facility as shown in the following equation (see Table 26).

$$\begin{array}{l} \text{Estimated upper limit} \\ \text{of number of patients} \\ \text{treated with} \\ \text{therapeutic ultrasound} \end{array} = \frac{\begin{array}{l} \text{Total number of} \\ \text{patients reported} \end{array}}{\begin{array}{l} \text{Total number of completed} \\ \text{and blank signed forms} \\ \text{returned} \end{array}} \times \begin{array}{l} \text{Total number of} \\ \text{forms sent out} \end{array}$$

This will almost certainly over-estimate the number of patients treated and is thus used as an upper bound. The estimated upper limit of number of patients is 1 500 000. Thus, there were between 850 000 and 1 500 000 treated with therapeutic ultrasound in 1977.

Device operator and calibration

The majority of ultrasound therapy devices are used by physiotherapists (62.7 percent), as shown in Table 8; 34.2 percent of ultrasound therapy devices are shown to be used by chiropractors. A total of 72.5 percent of operators reported training in ultrasound therapeutic techniques (Table 10). Of those who specified the type of training, the most frequently reported was during a physiotherapy or chiropractic course.

It is interesting to note in Table 11 that a few medical doctors using ultrasound therapy devices favour Burdick and Birtcher as manufacturers of instruments, while physiotherapists seem to prefer Siemens and Burdick, and chiropractors Amrex and Mettler.

Only just over 70 percent of the respondents indicated whether or not ultrasound therapy devices were calibrated, 47 percent of the respondents indicating that the device was calibrated (Figure 8). Of those indicating calibration, 39 percent reported calibration by the manufacturer, 20 percent by the hospital and 41 percent by others. The frequency of calibration information was combined with the question of whether the device was regularly calibrated, since this question was somewhat poorly worded. This results in a total of 30 percent of the respondents reporting that their devices were calibrated more frequently than once per year.

Adverse effects

Adverse effects are listed in Table 12 and detailed in Appendix D. Of the 972 facilities, 80 adverse effects were reported. As can be seen from Table 12, these generally fall within known contraindications. In questionable cases letters were sent to the respondents and in all cases where replies were received this remained true. Seven cases (8.8 percent) reported that dizziness, nausea and fatigue are of more concern.

DIAGNOSTIC ULTRASOUND

Number of devices

From the data collected (Figures 9, 10, Table 13, 14), it can be seen that a relatively small number of hospitals (8.3 percent) reported use of ultrasound as a diagnostic tool. Only hospitals reported use of diagnostic ultrasound. An estimate of the number of hospitals using diagnostic ultrasound was based on the ratio of completed filled returns to blank signed returns from hospitals. This gave a total estimate of 15.2 percent of hospitals using diagnostic ultrasound. However, this will most likely over-estimate the number of hospitals and is thus used as an upper bound. Thus, there were between 8.3 percent and 15 percent of hospitals using diagnostic ultrasound in Canada in 1977.

The regional distribution of hospitals using ultrasound as a diagnostic tool was roughly proportional to the population of each province, (Table 14, Figure 9, Table 25), almost 40 percent of facilities being located in Ontario.

The average number of devices per hospital reporting the use of diagnostic ultrasound is 3.5. This varies in the various provinces, with a low 1.1 devices per facility in Saskatchewan and a high of 4.3 devices per facility in Ontario.

Manufacturers and types of devices

Forty manufacturers and distributors of diagnostic ultrasound devices are listed in Appendix C. Not all of these could be identified or located. As can be seen from Table 16, two manufacturers account for 28.7 percent of the devices used, and the major 14 manufacturers account for 85.3 percent of the devices used. Those unidentified in Appendix C mainly report one or two devices each.

Treatment

The facilities which reported the use of diagnostic ultrasound indicated that diagnostic ultrasound is most commonly used in cardiology and cardiovascular surgery hospital services. This is followed in order by obstetrics, radiology and neurology (Table 17).

It appears that continuous wave mode and pulsed wave mode of ultrasound are used almost equally, the mean time of exposure varying from about 12 to 20 minutes (Table 18). Of the respondents 25.7 percent gave information on pulsed duration, only one of these being greater than the 60-minute range set in Table 18 (this being for 120 minutes); 30.5 percent of the respondents gave information on duration times for continuous wave mode of operation. However, 22 of these were out of the 60-minute range set in Table 18. Of these, one reply reported 90 minutes duration, four reported 180 minutes, twelve reported 240 minutes, four reported 600 minutes and one reported 1400 minutes. Some of these replies are probably due to fetal monitoring, which requires up to several hours of continuous wave monitoring. However, it is unlikely that exposure continued for more than 23 hours. Other replies appear to be in error, e.g., the minimum exposure duration for continuous wave mode was 1 minute. Figure 11 shows the distribution of continuous wave mode ultrasound duration reported. It can be seen that 28 percent of the respondents reported a 10-minute duration, and the majority of replies were between 0 and 30 minutes. Figure 12 shows a similar distribution for pulsed wave mode ultrasound. Here the most commonly reported durations were 10 minutes and 30 minutes, with the majority of replies between 0 and 30 minutes.

No meaningful data was obtained on the ultrasound intensity levels of diagnostic devices. Only 8.7 percent reported intensity levels for the continuous wave mode, and 15 percent for the pulsed wave mode of ultrasound. Further, less than 4 percent reported the duty cycle between 0 and 100 percent. This data is not always readily available in a case of ultrasound diagnostic devices, and is not even necessarily provided in the user manuals.

Of the respondents 73.4 percent replied to the question of diagnostic ultrasound frequency used. Of these 22.9 percent gave a frequency of 2.25 MHz, 12.3 percent gave 2.00 MHz and 12.3 percent gave a frequency of 3.5 MHz.

More than 1.2 million patients/examinations were reported for diagnostic ultrasound in 1977. A detailed look at the completed returns shows that the actual number of patients is approximately 340 000 (Figure 13, Table 27). The reason for this is that while the question asked for the number of patients examined per device in 1977, in the reported returns there was some confusion between the number of patients examined, the number of patients examined per device, and the number of examinations. Detailed analysis of the replies showed that 75.5 percent reported 3800 or less patients examined per year per device, 0.5 percent reported 3800 - 5000 patients examined per year per device, and 24.0 percent reported 10 000 patients examined per year per device. In addition, the number of replies decreased steadily for an increasing number of patients except for the large number reporting 10 000 patients. A check with hospitals confirmed that 3800 patients was a reasonable maximum limit per device. A recalculation on this basis gives 340 000 patients examined by diagnostic ultrasound in 1977.

In addition, an estimate of the total number of patients examined using diagnostic ultrasound was based on the ratio of completed filled returns to blank signed returns for each hospital as shown in the following equation (figures from Table 27)

$$\begin{array}{lcl} \text{Estimated upper} & & \text{Reported no. of patients} \\ \text{limit of no. of} & & \text{in hospitals} \\ \text{patients examined by} & = & \frac{\text{Completed plus blank}}{\text{signed returns for hospitals}} \\ \text{diagnostic ultrasound} & & \times \text{No. of forms} \\ & & \text{sent to} \\ & & \text{hospitals} \end{array}$$

This will almost certainly overestimate the number of patients examined and is thus used as an upper bound. The estimated upper limit of patients examined is 620 000. Thus, there were between 340 000 and 620 000 patients examined by diagnostic ultrasound in 1977.

Device operator and calibration

It was indicated that the majority of diagnostic ultrasound devices are operated by medical doctors (62.2 percent), and ultrasound technicians (31.0 percent) (Table 19). However, 55.9 percent of "other" operators were also indicated. Table 20 lists the "other" professions reported using ultrasound diagnostic devices. It can be seen that these are mainly nurses and technicians. Only 44.3 percent reported training in diagnostic ultrasound techniques (Table 21). However, very little specific information regarding the type and duration of training was obtained.

It is interesting to note that medical doctors operating diagnostic devices appear to favour Parks and Picker manufacturers, whereas ultrasound technicians seem to use Picker more often, and other professions Parks (Table 22).

Approximately 70 percent of the respondents indicated if the devices were calibrated; 45 percent reported regular calibration (Figure 14). The calibration was most frequently done by the manufacturer. The frequency of calibration information was combined with whether or not the ultrasound equipment was regularly calibrated, and this was due to the poor wording of the question. This resulted in 44 percent of the total respondents reporting calibration more frequently than once a year.

Adverse effects

Only two adverse effects were reported for ultrasound diagnostic devices, one answer being a false diagnosis, and the other not stated and with no further response by a follow-up letter.

OTHER ULTRASOUND DEVICES

No surgical medical ultrasound devices were reported. However, this may not indicate that there is no use of surgical ultrasound in Canada, as the forms may not have been directed to all hospital departments. It would indicate, however, that very little surgical ultrasound is conducted in Canada.

No further analysis was conducted of the 67 miscellaneous non-medical ultrasound devices reported, since the survey was not concerned with non-medical ultrasound usage.

TABLE 27

Number of Patients Examined by
Diagnostic Ultrasound

No. Facility	No. of forms sent out	No. of com- pleted forms returned	No. of blank signed forms returned	No. of patients/ treat- ments reported	No. of patients reported	Estimated upper limit of number of patients examined
Hospitals	1 341	111	619	1 216 770	340 000	620 000

5. CONCLUSIONS

In 1977, 1521 ultrasound devices providing therapy to between 850 000 and 1.5 million patients[†] were surveyed. Prior surveys (1, 2, 3) have shown that therapeutic devices rarely deliver the prescribed ultrasound dose. This emphasizes the need for performance standards for these devices. Ultrasound Therapy Devices Regulations have been published in Part I of the Canada Gazette (4).

Between 340 000 and 620 000 patients[†] were examined using 393 diagnostic ultrasound devices in 1977. The sale of these diagnostic devices is expected to double between 1980 and 1983 (5). This rapid expansion, combined with an increasing number of applications, will result in a large proportion of the Canadian population being exposed to diagnostic ultrasound. Thus it is important to monitor the performance of these devices carefully with a view to possible future standards.

The surgical non-imaging applications of ultrasound appear to be minimal in Canada. However, although the intensities of ultrasound used in surgery are extremely high, they are normally used by specialists in the field. The frequency of use and applications of this modality should continue to be monitored since the potential for adverse effects exists if used by unqualified personnel.

This survey was conducted in conjunction with one for microwave and shortwave diathermy devices and did not include dental ultrasound uses.

This survey provided sufficient data on the diagnostic and therapeutic applications of ultrasound to be of considerable use in developing performance standards and safety guidelines.

†Footnote: Some misinterpretation occurred in the question related to the numbers of patients treated or examined. Some responses indicated the number of treatments or examinations instead of the number of patients treated or examined. Thus ranges were determined which are the statistical estimates of the upper and lower limits for these values.

REFERENCES

1. Stewart H.F., Harris G.R., Herman B.A., Robinson R.A., Haran M.E., McCall G.R., Carless G. and Rees D., 1974, "Survey of Use and Performance of Ultrasonic Therapy Equipment in Pinellas County, Florida", *Phys. Therapy* 54(7), 707-715.
2. Stewart H.F., Harris G., Robinson R. and Garry J., 1974, "Survey of Use and Performance of Ultrasonic Therapy Units in the Washington, D.C. Area", in: *Health Physics in the Healing Arts*, Publication (FDA) 73-8029, March (Washington, D.C.: Department of Health, Education and Welfare).
3. Repacholi M.H., Benwell D.A., (1979), "Using Surveys of Ultrasound Therapy Devices to Draft Performance Standards", *Health Physics*, Vol. 36, pp. 679-686.
4. *Ultrasound Therapy Regulations*, (1979), *Canada Gazette*, Part I, No. 37, Vol. 113, pp. 5795-5800.
5. *U.S. Market Forecast 1980*, (1980), *Electronics*, January 3, pp. 134-137.

APPENDIX A

Survey Questionnaire

SURVEY OF ULTRASOUND MEDICAL APPLICATIONS

Is the name and address label correct?

Yes

No

If "No", please provide correct information below:

Name

Address

Postal Code

1. Does your institution/clinic provide diagnostic ultrasound services?

Yes

No

If "Yes", specify in which medical services ultrasound is used as a diagnostic or surgical tool:

Neurology — Neurosurgery

Cardiology

Obstetrics — Gynaecology

Ophthalmology

General Surgery

Cardiovascular Surgery

Urology

Radiology

Emergency

Other

(specify)

2. Does your institution/clinic provide therapeutic ultrasound services?

Yes

No

If "Yes", specify what parts of the body are treated:

Extremities

Upper trunk

Lower trunk

Head

(specify)

Pelvic Region

(specify)

3. The following questions apply to ultrasonic equipment or instruments which are used for diagnostic, surgical and/or therapeutic purposes in the institution/clinic:

3. The following questions apply to ultrasonic equipment or instruments which are used for diagnostic, surgical and/or therapeutic purposes in the institution/clinic:																															
	Manufacturer	Model Number	Number of units of each model	Approximate number of patients treated/ diagnosed per year	Per treatment, continuous wave		Per treatment, pulsed mode			Transducers (Applicator Heads)			Profession of each operator of equipment or instruments (please provide number of operators)					Are the operators trained in ultrasound?		Is the ultrasound equipment regularly calibrated?						Adverse effects due to ultrasonic diagnostic procedure or treatment?					
					Duration (minutes)	Exposure (W/cm ²)	Duration (minutes)	Exposure (W/cm ²)	Duty cycle (%)	Manufacturer	Model Number	Frequency (M. Hz.)	Medical doctor	Physiotherapist	Chiropractor	Qualified ultrasound tech.	Other (specify)	Yes (see Question 4)	No	Yes	No	If "Yes", by whom			If "Yes", how frequently			Yes (see Question 5)	No		
																						Hospital/ clinic	Manufacturer	Other	Never	Less than once a year	More than once a year				
DIAGNOSTIC APPLICATIONS		026	027	028	029	030	031	032	033	034	035	036	037	038	039	040	041	042	043	044	045	046	047	048	049	050	051	052	053	054	
	a.	055	056	057	058	059	060	061	062	063	064	065	066	067	068	069	070	071	072	073	074	075	076	077	078	079	080	081	082	083	
	b.	084	085	086	087	088	089	090	091	092	093	094	095	096	097	098	099	100	101	102	103	104	105	106	107	108	109	110	111	112	
	c.	113	114	115	116	117	118	119	120	121	122	123	124	125	126	127	128	129	130	131	132	133	134	135	136	137	138	139	140	141	
SURGICAL APPLICATIONS		142	143	144	145	146	147	148	149	150	151	152	153	154	155	156	157	158	159	160	161	162	163	164	165	166	167	168	169	170	
	a.	171	172	173	174	175	176	177	178	179	180	181	182	183	184	185	186	187	188	189	190	191	192	193	194	195	196	197	198	199	
	b.	200	201	202	203	204	205	206	207	208	209	210	211	212	213	214	215	216	217	218	219	220	221	222	223	224	225	226	227	228	
	c.	229	230	231	232	233	234	235	236	237	238	239	240	241	242	243	244	245	246	247	248	249	250	251	252	253	254	255	256	257	
THERAPEUTIC APPLICATIONS		258	259	260	261	262	263	264	265	266	267	268	269	270	271	272	273	274	275	276	277	278	279	280	281	282	283	284	285	286	
	a.	287	288	289	290	291	292	293	294	295	296	297	298	299	300	301	302	303	304	305	306	307	308	309	310	311	312	313	314	315	
	b.	316	317	318	319	320	321	322	323	324	325	326	327	328	329	330	331	332	333	334	335	336	337	338	339	340	341	342	343	344	
	c.																														

4. If operators are trained in ultrasound, please give description, location and duration of the course:

5. If adverse effects were observed due to diagnostic, surgical or therapeutic ultrasound, please describe:

Name of person completing questionnaire

Title

Date

(Area Code) Telephone No.

APPENDIX B

Manufacturers and Distributors of Therapeutic Ultrasound Devices

Advanced Trends

Amrex

Birtcher

Burdick

Dallons

EMS

Elmed

Emile Michel

Fischer, H.G.

Fisher, R.A.

ITO

Lindquist, R.J.

Martin

Medco

Medelco

Mettler

Nordelectro

Rank Precision

Richmar

Reinbeck

Siemens

Sterne

Three M

Ultrashell-Geratebeau

Ultrason

APPENDIX C

Manufacturers and Distributors of Diagnostic Ultrasound Devices

ADR	Searle
Amsco	Siemens
Bach-Simpson	Sonicaid
Berkeley	Sonometrics
Corometrics	Ultrasound Scientific Industries
Delelande	Unirad
Dentsply	Varian
Devilbiss	Wakeling
Diagnostic Electronics	
Hewlett Packard	
Highstoy	
Hoffman Laroche	
Hoffrel	
Honeywell	
Irex	
Ivac	
Kretz	
Kontron	
L and R Mfg. Co.	
Life Sciences	
Medelec	
Medsonics	
Metrix	
Mettler	
Nuclear Enterprises	
Overseas Monitor	
Parks	
Picker	
Physio-Control	
Radionics	
Rohe	
S.K.I. (Smith Kline Industries)	

APPENDIX D

List of Adverse Effects Reported for Therapeutic Ultrasound Devices

Form Number	Device Manufacturer	Reported Effect
100013	Burdick	Occasional immediate exacerbation of pain
100041	Burdick	Burn-like lesion elbow
1100011	Amrex	Patient tense and edgy
120102	Burdick	Pain with power increase
120114	Burdick/Birtcher	Occasional pain
120124	Siemens	Pain on c.w. over bony prominences
2400631	Birtcher	Epidermal irritation
240301	Siemens	Occasional pain after treatment
240326	Not stated	Occasional pain
3500072	Not stated	Temporary increased pain on occasion
3500082	Siemens	Never use over growing bones, fractures, etc.
3500232	Not stated	Occasional irritation effects
3500252	Burdick	Occasional increase in pain
3500282	Siemens	Patients with "dermographia" blistered
3500292	Mettler	Occasional discomfort after treatment
3500542	Not stated	Occasional increase in pain
3500592	Siemens	Increased soreness in treated area
3500602	Elmed	Occasional increased pain
3500681	Not stated	Temporary aching
3500691	Elmed	Two cases of mild dermal irritation
3500722	Dallons/Siemens	Increased pain
3501751	Medco	Occasional pain in some areas
3501941	Not stated	Tissue response of cancer tissue
3502541	Amrex	Occasional stab of pain
3502981	Medco	Occasional overheating on continuous wave
3503231	H.G. Fischer	Occasional pain
3503461	Not stated	Seldom irritation of the area
3504421	Richmar	Occasionally if used over inflamed area
3504701	Not stated	Causes pain in a torn meniscus (knee)
3505131	Not stated	Occasional pain
350618	Not stated	Occasional complaint of increased discomfort
350631	Siemens	Occasional uncomfortable sensory stimuli

Form Number	Device Manufacturer	Reported Effect
350665	Siemens	Occasional fatigue and nausea after treatment
350667	Siemens/EMS	Stabbing pains over bony areas
350677	Burdick	Increase in pain after treatment
350687	Mettler	Increase of pain after treatment of some
350707	Not stated	Increased periosteal pain
350710	Not stated	Occasional expected burning or numbing feeling
350730	Amsco Electronics	Ear damage to operator, wears protective ear muffs
350732	Siemens	Deep pain due to overdose
350737	Siemens	Due to allergies to transmission gel
350753	Not stated	Occasional increase in pain
350796	Siemens	Occasional increased pain
350814	EMS/Burdick	Occasionally excessive warmth
350825	Not stated	One occasion of mild earache
350882	Birtcher	Fatigue and heavy feeling in chest after
350899	Elmed	Occasional increased tenderness under sound
4600161	Not stated	Occasional burning sensation
4600531	Not stated	Allergic reaction to chemicals
471106	Birtcher	Skin abrasion on friable tissue
471113	Burdick	Increase in pain
471175	Burdick	Can increase pain
4800012	Burdick	Headaches
4800092	Birtcher	Occasional dizziness, pain and shocks
4800152	Burdick	Increase of pain, anemia, tiredness
4800233	Not stated	Occasional pain due to high intensity
4800271	Burdick	Residual neuralgia, temporary
481216	Burdick	Varicosities on arm after 2 applications
481241	Burdick	Nausea after paravertebral treatment
481266	Burdick	Burning sensation, pain and aching
481301	Not stated	Patients with acute lesions complain of increased pain about 4 hours following
481313	Birtcher	With inappropriate dosage, severe searing pain
5900073	Mettler	Temporary exacerbation of musculoskeletal symptoms
5900192	Siemens	Occasional increased pain

Appendix D (cont'd)

Form Number	Device Manufacturer	Reported Effect
5900272	Not stated	Questionable headache
5900492	Burdick	Weird feelings in head, sudden jab type pain
5900532	Not stated	Patients with acute soft tissue injuries of spine suffer increased discomfort
591405	Burdick	Over a five-year period, two cases of dizziness
591425	Birtcher	Occasional nausea lasting one hour
591433	Birtcher	Increased pain, nausea, lightheadedness
591444	Burdick	Increased pain in treatment underwater and of acute soft tissue lesions
591454	Not stated	Usual contraindications observed
591465	Siemens	Anxiety and restlessness in operator after treatments
591474	Dallons	Occasional increased sensitivity to pain
591510	Burdick	Occasional pain, start up, Burdick
3501151	Siemens	Not stated
3503441	Siemens	Not stated
350742	Dallons	Not stated
350842	Siemens	Not stated

CA1 HW 1180E53

Canada. DNHW. EHD.

80-EHD-53

CANADA-WIDE SURVEY OF NON-IONIZING RADIATION
MEDICAL DEVICES. PAR II. ULTRASOUND DEVICES.

**RESOURCE CENTRE
INST. FOR ENVIRON'L. STUDIES
UNIVERSITY OF TORONTO**



